

(3) *Date PMA or notice of completion of a PDP is required:* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before May 22, 2024, for any multiple use blood lancet for multiple patient use described in paragraph (d)(1) of this section that was in commercial distribution before May 28, 1976, or that has, on or before May 22, 2024, been found to be substantially equivalent to a multiple use blood lancet for multiple patient use described in paragraph (d)(1) of this section that was in commercial distribution before May 28, 1976. Any other multiple use blood lancet for multiple patient use shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: November 16, 2021.
Lauren K. Roth,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2016–N–0400]

Medical Devices; General and Plastic Surgery Devices; Reclassification of Blood Lancets

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).
ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing a final order to reclassify three types of blood lancets used to puncture skin to obtain a drop of blood for diagnostic purposes from class I (general controls) exempt from premarket notification into class II (special controls) and subject to premarket notification, specifically, single use only blood lancets with an integral sharps injury prevention feature, single use only blood lancets without an integral sharps injury prevention feature, and multiple use blood lancets for single patient use only. FDA is designating special controls for these three types of blood lancets based on the determination that general controls only are not sufficient and there is sufficient information to establish special controls to provide a reasonable assurance of their safety and effectiveness. FDA is also reclassifying a fourth type of blood lancet, multiple use blood lancets for

multiple patient use, from class I (general controls) exempt from premarket notification into class III (premarket approval). FDA is reclassifying these four types of blood lancets on its own initiative based on new information.
DATES: This order is effective November 22, 2021. See further discussion in section VI, Implementation Strategy.
FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993, 301–796–6527, Rebecca.Nipper@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911, Stephen.Ripley@fda.hhs.gov.
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I. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation or acronym	What it means
510(k)	Premarket Notification.
515(b) Proposed Order	Proposed Order calling for premarket approval applications for class III blood lancets published on March 3, 2016 (81 FR 11151).
513(e) Proposed Order	Proposed Order to reclassify blood lancets published on March 3, 2016 (81 FR 11140).
Agency	Food and Drug Administration.
CDC	Centers for Disease Control and Prevention.
CFR	Code of Federal Regulations.
EPA	Environmental Protection Agency.
FDA	Food and Drug Administration.
FDASIA	Food and Drug Administration Safety and Innovation Act.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FR	Federal Register.
HIV	Human Immunodeficiency Virus.
OMB	Office of Management and Budget.
Panel	General & Plastic Surgery Devices Panel of the Medical Devices Advisory Committee, device classification panel on June 26, 2013.
PDP	Product Development Protocol.
PMA	Premarket Approval Application.
PRA	Paperwork Reduction Act of 1995.
PT/INR	Prothrombin Time and International Normalized Ratio.
Ref	Reference.
UDI	Unique Device Identifier.
UPC	Universal Product Code.
U.S.C	United States Code.

II. Background

A. Classification

The Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 *et seq.*), as amended, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments on May 28, 1976 (generally referred to as “preamendments devices”) are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

B. Reclassification

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final order for reclassifying a device. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the **Federal Register**; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket.

FDA published a proposed order in the **Federal Register** of March 3, 2016 (81 FR 11140), held a device classification panel meeting of the General & Plastic Surgery Devices Panel of the Medical Devices Advisory Committee, on June 26, 2013 (the Panel), as described in section 513(b) of the FD&C Act with respect to the four different types of blood lancet devices, and considered comments from public dockets. Therefore, FDA has met the requirements under section 513(e)(1) of the FD&C Act.

C. Requirement for Premarket Approval

Elsewhere in this issue of the **Federal Register**, FDA has published a final order requiring the filing of a premarket approval application (PMA) or notice of completion of a product development protocol (PDP) for multiple patient blood lancets (class III). In practice, the

option of filing a notice of completion of a PDP has rarely been used by manufacturers. For simplicity, while corresponding requirements for PDPs remain available to manufacturers in response to a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)), this document will refer only to the requirement for the filing and obtaining approval of a PMA.

III. Public Comments in Response to the Proposed Order

In the **Federal Register** of March 3, 2016, FDA published a proposed order to reclassify single patient use blood lancets from class I (general controls) exempt from premarket notification to class II (special controls) and to reclassify multiple patient blood lancets from class I (general controls) exempt from premarket notification to class III (premarket approval) (513(e) Proposed Order, 81 FR 11140). On that same date, FDA also published a proposed order to require the filing of a PMA for multiple patient blood lancets (515(b) Proposed Order) (81 FR 11151). The proposed orders also stated that FDA proposed to amend 21 CFR part 878 to create a separate regulation under § 878.4850 (21 CFR 878.4850) for all blood lancet types (previously identified with product codes FMK or JCA). The comment periods for both proposed orders closed on June 1, 2016.

The March 3, 2016, 513(e) Proposed Order received approximately 150 comments from industry, professional societies, trade organizations, and individual consumers by the close of the comment period. Certain comments have been grouped together under a single comment since the theme of the comments are similar in nature. The grouped comments and FDA’s response to each grouping are summarized in this section. The number assigned to each comment is purely for organizational purposes and does not signify the comment’s value, importance, or the order in which it was received.

As previously set forth in the 513(e) Proposed Order, FDA identified the following four subsets of blood lancet devices:

1. A single use only blood lancet with an integral sharps injury prevention feature is a disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base (including an integral sharps injury prevention feature) that is used to puncture the skin to obtain a drop of blood for diagnostic purposes. The integral sharps injury prevention feature allows the device to be used once and then renders it

inoperable and incapable of further use (“subset 1”);

2. A single use only blood lancet without an integral sharps injury prevention feature is a disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes (“subset 2”);

3. A multiple use blood lancet for single patient use only is a multiple use capable blood lancet intended for use on a single patient that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes (“subset 3”); and

4. A multiple use blood lancet for multiple patient use is a multiple use capable blood lancet intended for use on multiple patients that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes (“subset 4”).

(Comment 1) Several comments generally agreed with the proposed reclassification of all four types of blood lancet devices. Some comments supported the proposed precautions and labeling special controls as necessary for healthcare providers and users of single patient use blood lancets. Other comments agreed that the risks to public health associated with use of multiple use blood lancets for multiple patients are sufficiently significant for FDA to reclassify this device type into class III (premarket approval).

(Response 1) After considering the Panel’s recommendations and examination of scientific information (Ref. 1, and previously described in the 513(e) Proposed Order (81 FR 11140 at 11142), FDA continues to believe that there is sufficient evidence to establish special controls that, together with general controls, provide a reasonable assurance of safety and effectiveness to reclassify single patient use only blood lancets to class II, as initially specified in the 513(e) Proposed Order. Further, FDA continues to believe that blood lancets for multiple patient use present a potential for unreasonable risk of illness or injury, that insufficient information exists for FDA to determine that special controls would provide a reasonable assurance of safety and effectiveness of the device, and that blood lancets for multiple patient use should be reclassified into class III.

(Comment 2) Several comments stated that the evidence for a risk of infection was associated with the use of blood lancets in a professional care setting and therefore there was no evidence to

support reclassification of personal blood lancet devices in home use environments.

(Response 2) FDA disagrees with the comments that there is no evidence to support the reclassification of single patient use blood lancets for home use from class I (general controls) to class II (special controls). At the Panel meeting on June 26, 2013, FDA presented an analysis of the risks to health associated with the use of blood lancets and new scientific data supporting these risks (Ref. 2). Although the information on infection transmission was generated in healthcare settings, FDA believes the risks to health are general risks that apply to all single use patient blood lancets, regardless of the environment in which they are used. Based on the scientific evidence available to the Agency at that time, blood may be transmitted between patient and care givers by the misuse of “single use only” medical devices that are not intended for or labeled for reuse, because they are not designed to be cleaned or sterilized to become safe for reuse, such as needles or syringes (Ref. 2). Similarly, transmission may also occur if validated cleaning and disinfection instructions are not identified and followed for multiple use blood lancets for single patient use only (subset 3). After reviewing the new scientific data supporting the identified risks to health, the Panel recommended that reclassifying single patient use blood lancets from class I (general controls) to class II (special controls) will provide a reasonable assurance of the safety and effectiveness of blood lancets for single patient use.

The Panel also acknowledged that many of the adverse event reports of device problems indicate that accidental sticks are most likely when safety features malfunction, the lancet is difficult to remove, or when lancets are too dull to pierce the skin or too long to fit within the safety caps (Ref. 2). From January 1, 2015, to May 31, 2021, FDA received over 3,100 reports for blood lancets, most of which are device malfunctions. The most commonly reported problems include accidental blade sticks, the blade breaking off or remaining in a patient's finger, and the blade protruding from the device cap or not retracting. In addition, FDA received numerous reports of device malfunctioning and retraction problems with the blood lancets.

FDA agrees with the Panel that reclassification from class I to class II is appropriate for single patient use blood lancets and is supported by FDA's findings reported in the 513(e) Proposed Order, adverse event reporting, and the

panel executive summary (Ref. 2). FDA also agrees with the Panel that premarket notification (510(k)) submissions are necessary for single patient use blood lancets to ensure adequacy of the labeling concerning the limitation to single patient use only, effective sharps injury prevention features that disable the lancet from further use (when applicable), and blade dispense release mechanisms on multiple use blood lancets for single patient use only, as well as instructions for a safe blade disposal and cleaning and disinfection for the multiple use blood lancets for single patient use only. These special controls are consistent with the special controls applicable to other similar device technology such as injection needles (Ref. 2). As a result, FDA believes the premarket notification requirement and the established special controls are necessary to provide a reasonable assurance of safety and effectiveness for all for single patient use blood lancets, whether they are used in a home environment or a healthcare setting.

(Comment 3) Several comments stated that the 513(e) Proposed Order, if finalized, would increase the cost of blood lancets for single patient use, putting an undue burden on patients, and would cause what one comment referred to as “economic driven disruption . . . with lancet access driving use of less expensive devices” in the wrong setting.

(Response 3) FDA appreciates the economic concerns raised by users of blood lancets regarding the cost of this device; however, reclassification decisions are based on the level of controls necessary to ensure that reasonable assurance of safety and effectiveness requirements under 21 CFR 860.7(d) and (e) as well as section 513(e) of the FD&C Act are met. The regulatory requirements for blood lancets established by FDA are based on the probable benefits to health for the indications for use of blood lancet devices and the risk of the devices when used as intended, and not the costs of the device. FDA also agrees with the findings of the Panel and believes that to mitigate the known risks to health posed by these devices, the proposed special controls are necessary for single patient use only blood lancets, regardless of their environment of use. In addition, FDA believes that manufacturers of single patient use only blood lancets may already be complying with some of the proposed special controls (e.g., biocompatibility testing and package integrity testing) because they are industry standard type tests (Ref. 2). Therefore, FDA does not believe

the reclassification of single patient use only blood lancets (subsets 1, 2, or 3) will result in an economic disruption that will affect the availability of or patient access to these devices for these intended purposes.

(Comment 4) Several comments stated that the proposed special controls related to the disinfection of skin and/or reusable device components for single patient use blood lancets (subsets 1, 2, or 3), along with the associated special controls concerning labeling and validation, were either too burdensome or not appropriate. For example, one comment did not understand why disinfection was needed for a single patient home use device; a similar comment felt that cleaning and disinfection validation was overly burdensome for single patient home use devices. A few comments stated that disinfection of the skin would adversely affect blood glucose monitoring by resulting in vasoconstriction. Also, one comment suggested that FDA should not mandate usage of Environmental Protection Agency (EPA) commercially registered disinfectant if a commonly available generic disinfectant agent is equally effective for home use.

(Response 4) FDA believes that the special controls related to the disinfection of reusable device components, along with the associated special controls pertaining to labeling and validation, are appropriate to ensure a reasonable assurance of safety and effectiveness for multiple use blood lancets for single patient use (*i.e.*, subset 3). To reduce the risk of infection, FDA believes that reusable components of single patient use lancets, such as reusable bases, should be adequately cleaned and disinfected (*i.e.*, reprocessed) between uses. Without adequate reprocessing validation conducted initially by the manufacturer for multiple use blood lancets for single patient use under simulated use conditions, it is unclear whether adequate labeling for cleaning and disinfection between uses by the end user can be developed. Further, patient soil (*e.g.*, skin cells, oil, dirt, skin flora, and body fluids such as blood and sweat) can accumulate on the reusable component over time, creating an ideal environment for microbial growth. Although the lancet may be for single patient use, soil can become transferred from the reusable base component to the single-use lancet, thereby posing a risk of infection upon reuse of the device in the same patient.

At the Panel meeting, FDA presented an analysis of the risks to health associated with the use of blood lancets and new scientific data supporting these

risks. Beyond mitigating the risk of infection, the Panel felt that reprocessing validation was necessary to demonstrate the functionality of the device over its lifetime, since the device could degrade when subjected to multiple cleaning and disinfection cycles (Ref. 2). FDA's guidance entitled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" provides recommendations for validation methods and labeling for proper cleaning of reusable medical devices that are consistent with the special controls in this final order (Ref. 3). Furthermore, the special controls for proper cleaning and disinfection of reusable components in this final order are also consistent with the recommendations in FDA's guidances "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use" and "Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use," which concern devices that are used by some of the same patient populations as those using blood lancets, both in a home use and clinical environment (Refs. 1 and 4).

FDA continues to believe that use of EPA-registered disinfectants is necessary for cleaning and disinfection of the multiple use blood lancets for single patient use even for home use settings. FDA recommends utilizing disinfectants that are effective against bloodborne pathogens, such as Human Immunodeficiency Virus (HIV), Hepatitis B, and Hepatitis C viruses. FDA also recommends the use of EPA-registered disinfectants because they have been demonstrated to be effective against specific bloodborne pathogens when used for specified contact times. EPA-registered disinfectants, which include both commercially registered disinfectants and commonly available generic disinfectant agents, are not allowed to make efficacy claims against specific pathogens unless the EPA has reviewed data to support those claims.

FDA notes that preparation of skin is part of standard patient care prior to drawing blood from patients, and that current guidelines and standards (Refs. 5 and 6) generally include cleaning and disinfection of skin prior to capillary blood sampling. The purpose of this skin preparation step is to prevent infections caused by entry of microbial flora on the patient's skin into the puncture wound created by the blood lancet. Nonetheless, FDA recognizes that the skin preparation procedure may differ depending on the particular application and/or clinical use, and that specific guidelines may exist for skin preparation for certain clinical

applications. As such, FDA has revised the special control regarding "instructions on cleaning and disinfection of the skin to be pierced" to instead state "instructions on preparation (e.g., cleaning, disinfection) of the skin to be pierced."

As a result of the available scientific information, FDA has determined that labeling special controls are necessary to address safety risks associated with use as labeled, and possible misuse, of blood lancets. In particular, it is critical to have specific required labeling special controls related to the preparation of skin and reprocessing of blood lancets for single patient use devices to provide a reasonable assurance of safety and effectiveness.

(Comment 5) Several comments stated that the proposed labeling for single patient use only blood lancet devices is inadequate, overly prescriptive, and/or unnecessary for blood lancets used in home use environments.

(Response 5) FDA continues to believe that the labeling proposed as special controls for single patient use only blood lancets (subsets 1, 2, and 3) are necessary to provide a reasonable assurance of safety and effectiveness for these devices and believes the current labeling for blood lancets is inadequate. At the Panel meeting, FDA presented an analysis of the risks to health associated with the use of blood lancets and new scientific data supporting these risks. In the data that was presented, it was shown that the risk of bloodborne pathogen transmission was related to the improper use of blood lancets. FDA believes that additional labeling is needed to address this safety risk associated with misuse of blood lancets, including detailed descriptions of the proper use of the device and any sharps injury prevention feature, hand washing instructions for the user before and after use of the device, instructions on cleaning and disinfection of the device and to the skin to be pierced, and instructions for the safe disposal of the device (Ref. 2). For each environment of use for blood lancets, adequate labeling must be included to address either use of these devices in healthcare settings or labeling for home use that is written for the end users to be able to understand and follow the instructions.

FDA has determined that general controls alone are not sufficient to provide a reasonable assurance of safety and effective for these devices (subsets 1, 2, and 3), and there is sufficient information to establish special controls to provide such an assurance; therefore, FDA is reclassifying these devices into class II (81 FR 11140 at 11142). The Panel consensus was that single patient

use only blood lancets meet the statutory definition of a class II device and require labeling special controls related to the cleaning and disinfection of skin and blood lancets for single patient use devices to reasonably assure safety and effectiveness.

(Comment 6) Some comments stated that the proposed 180-day timeframe is too short for manufacturers of single patient use blood lancets (subsets 1 to 3) to demonstrate conformance with the required special controls and submit a premarket notification (510(k)). The comments recommended timeframes ranging from 1 to 2 years for the submission of new 510(k)s for these types of blood lancets.

(Response 6) FDA agrees with the commenters' concern that its proposal to not enforce compliance with the 510(k) requirement or special controls for single patient use only blood lancets until 180 days after the effective date of the final order may not be enough time for all manufacturers of single patient use blood lancets to implement the required special controls and receive 510(k) clearance for those devices without prior 510(k) clearance. The typical review time for a 510(k) is 90 days. However, if a 510(k) submission lacks the information necessary for the Agency to continue or complete review, FDA may issue a request for additional information to the submitter and place the 510(k) on hold pending receipt of a complete response to the identified deficiencies. FDA's current policy is to allow a sponsor 180 days to respond to a request for additional information,¹ resulting in a maximum review time of 270 days. Therefore, even if a submission were made on the effective date, there could be instances where a 510(k) submission would remain pending beyond 180 days after the effective date of the final order. FDA, therefore, does not intend to enforce compliance with the 510(k) requirement or special controls until 1 year after the effective date of this final order for blood lancets for single patient use only that have been offered for sale prior to the publication of this final order but do not already have a 510(k) clearance.

(Comment 7) There were several comments relating to the Unique Device Identification labeling and data submission requirements. These requirements apply to all devices in commercial distribution as of their established Unique Device

¹ See page 6 of Guidance for Industry and Food and Drug Administration Staff entitled "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals", available at <https://www.fda.gov/media/73507/download>.

Identification compliance date unless an exception or alternative applies. For those blood lancets that have been offered for sale prior to November 22, 2021, the comments: (1) Expressed concerns that the Unique Device Identification compliance date for class II and class III devices will have already passed when this order is published, and insufficient time will be provided to allow for compliance; (2) requested that a period of 2 or 3 years be provided for compliance with Unique Device Identification requirements; and (3) pointed out that industry anticipated that their class I devices would use the product's Universal Product Code (UPC) for purposes of unique device identifier (UDI) implementation as permitted under § 801.40(d) (21 CFR 801.40(d)), and that FDA has not provided a reasonable basis to remove these devices from this provision. These comments further requested that FDA grant a general exception or alternative to allow the devices subject to this order, regardless of their classification, to utilize their UPCs as their UDIs.

(Response 7) There are three principal elements to Unique Device Identification requirements: Labeling with a UDI, direct marking of devices that are intended to be used more than once and intended to be reprocessed between uses, and data submission to the Global Unique Device Identification Database (GUDID) (see § 801.20, 801.45, and 830.300 (21 CFR 801.20, 801.45, and 830.300)). In addition, the Unique Device Identification final rule (78 FR 58786, September 24, 2013) (UDI Rule) added § 801.18 (21 CFR 801.18), which requires certain dates on device labels to be in a standard format. As explained in the preamble to the UDI Rule, FDA aligned the compliance date for standard date format requirements under § 801.18 with the compliance date by which a device must bear a UDI on its label and packages under § 801.20 to avoid the need to make changes to a device label more than once to implement the requirements in the final rule.² FDA disagrees 2 or 3 years is necessary for compliance with Unique Device Identification labeling and data submission requirements. Rather, FDA considered the commenters' request for additional time for compliance with UDI requirements and believes that the compliance timeframes set forth in section VI of this order provide sufficient time for manufacturers to perform all the functions required to comply with UDI labeling and data submission requirements, including converting manufacturing processes and

associated inventory management, and submitting required information to GUDID. In addition, manufacturers should consult existing UDI compliance policies, which may be applicable to their reclassified devices. FDA's publicly available UDI web page³ contains a comprehensive listing of UDI guidance documents and compliance policies.

FDA also disagrees that manufacturers of blood lancets should be permitted to utilize their UPCs as their UDIs. As indicated in the preamble to the UDI Rule (78 FR 58786 at 58798) the exception in § 801.40(d) was purposely limited to class I devices due to their relative low risk. For the reasons stated in the preamble to this order, FDA no longer considers the blood lancet devices to be low risk and is reclassifying them into class II and class III. Therefore, the exception in § 801.40(d) will no longer apply to these devices, and FDA does not believe that a general exception or alternative to the UDI labeling requirements would not be appropriate. An individual labeler that believes a UPC rather than a UDI on its device label would provide for more accurate, precise, or rapid device identification or would better ensure the safety or effectiveness of the device, may submit a request for an alternative under 21 CFR 801.55.

(Comment 8) Several comments stated that the proposed special controls are unclear and unnecessary for blood lancets for single patient use blood lancets. Other comments specifically requested clarification of the following special controls: (1) Design characteristics related to single use only blood lancets without an integral sharp injury prevention, (2) possible recognized consensus standards for mechanical performance testing, (3) sterility testing for the lancet only, and (4) FDA identification of recognized consensus standards for biocompatibility testing and clarification on whether testing should be completed for the finished product or only the lancet.

(Response 8) FDA continues to believe that special controls are necessary for single patient use only blood lancets. At the Panel meeting, FDA presented an analysis of the risks to health associated with the use of blood lancets and new scientific data supporting these risks. These risks to health are summarized in tables 1 to 3 of the 513(e) Proposed Order (81 FR 11140 at 11147). After deliberation, the Panel concluded that the risks to health warranted reclassification of blood

lancets from class I devices, as general controls were deemed insufficient to provide a reasonable assurance of safety and effectiveness. The proposed special controls are intended to inform manufacturers of the testing and information FDA believes to be necessary to provide a reasonable assurance of safety and effectiveness during the use of blood lancets, including single patient use only blood lancets.

FDA understands the confusion regarding the special control for single use only blood lancets without an integral sharps injury prevention feature regarding design to prevent sharp object injuries. The special controls for single patient use only blood lancets established by this final order are necessary to provide a reasonable assurance of safety and effectiveness for those devices. Each subset of blood lancets presents similar risks to health, but requires different special controls due to their different design characteristics and risk profiles. Design characteristics for blood lancets without an integral sharp injury prevention feature must still address the risks of sharp object injuries and bloodborne pathogen transmissions (see § 878.4850(b)(2)(i)). Examples of how this could be achieved include, but may not be limited to, the inclusion of a cap or blade cover. As described in the 513(e) Proposed Order (81 FR 11140) and adopted in this final order, these risks are also mitigated by mechanical performance testing to prevent device breakage and labeling. FDA believes that to satisfy the mechanical testing special control manufacturers must demonstrate injury prevention features (as applicable) and blade performance in single use single patient devices (see § 878.4850(a)(2)(ii) and (b)(2)(ii)); however, there is currently no FDA-recognized consensus standard for mechanical tests, methods, or acceptance criteria for this device type.

At the Panel meeting, FDA presented an analysis of the risks to health associated with the use of blood lancets and new scientific data supporting these risks. FDA believes that reusable components of single patient use devices, such as reusable bases, should be adequately cleaned and disinfected (*i.e.*, reprocessed) between uses in order to prevent risk of infection. Sterility testing is applicable to any device component that breaches the skin, thereby contacting the underlying sterile tissue and/or blood in order to mitigate the risk of infection. While this requirement commonly applies to the blade of the blood lancet device, it may be possible for other components of a

² See 78 FR 58786 at 58795, September 24, 2013.

³ Available at: <https://www.fda.gov/udi>.

blood lancet besides a “blade” to breach the skin. Therefore, FDA has determined that the sterility special control should be revised to clearly state that this special control applies to “any device component that breaches the skin (e.g., the blade)” for the three single patient use subtypes of blood lancets. The special control for biocompatibility testing must be conducted on the final finished form for the finished blood lancet device and is important to address the risk of adverse tissue reaction (not infection).

Manufacturers are encouraged to review the relevant FDA guidance documents including, but not limited to the “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile” (Ref. 7) and “Use of International Standard ISO 10993–1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing Within a Risk Management Process” (Ref. 8) for recommendations on how to comply with the special control testing requirements.

Evidence of compliance with the special controls is required to demonstrate reasonable assurance of safety and effectiveness and to support 510(k) clearance. As stated above, FDA does not intend to enforce compliance with the premarket notification (510(k)) requirement and special controls for blood lancets for single patient use only that have been offered for sale prior to the publication of this final order but do not already have a 510(k) clearance. However, 1 year after the effective date of this order, any: (1) Single use only blood lancet with an integral sharps injury prevention feature that does not comply with the special controls established in § 878.4850(a)(2), (2) single use only blood lancet without an integral sharps injury prevention feature that does not comply with the special controls established in § 878.4850(b)(2), or (3) multiple use blood lancet for single patient use only established in § 878.4850(c)(2), will be considered adulterated and misbranded (sections 501(f)(1)(B) and 502(o) of the FD&C Act (21 U.S.C. 351(f)(1)(B) and 352(o))) until such time as the device complies with the special controls and any premarket notification requirements.

(Comment 9) A comment stated that currently marketed blood lancets should be exempt from design controls because the safety concerns raised by those single patient use devices are related to the labeling and the use of blood lancets generally and not with the design of the device. Instead the comment suggests a phased-in approach for design control compliance for currently marketed

devices, depending on whether they meet the requirements pursuant to § 807.81(a)(3) (21 CFR 807.81(a)(3)).

(Response 9) FDA disagrees with this comment. The lancet blade is designed to pierce the skin and draw blood and can present a puncture hazard to anyone coming into contact with the device when the blade is accessible. This hazard is associated with serious risks as described in the 513(e) Proposed Order (81 FR 11140). Without the application of design controls (21 CFR 820.30), FDA is unable to verify that appropriate controls are in place to ensure that blood lancet devices are designed and tested in such a way as to perform as intended under the labeled conditions of use, and to provide a reasonable assurance of safety and effectiveness. Therefore, FDA does not intend to allow a phased-in approach for design control compliance of currently marketed single patient use blood lancets.

(Comment 10) A comment stated that the single patient use only blood lancet devices should be exempt from premarket notification under section 510(m) of the FD&C Act (21 U.S.C. 360(m)) and suggested that special controls could be documented in the Design History File (DHF) for FDA’s review during routine audits/inspections.

(Response 10) FDA does not agree that it is appropriate to exempt single patient use only blood lancets from premarket notification at this time. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance that the Agency issued on February 19, 1998, entitled “Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff” (Class II 510(k) Exemption Guidance) (Ref. 9). Based on the scientific information available to the Agency at this time and summarized in the 513(e) Proposed Order, FDA has determined these factors currently are not met for single patient use only blood lancet devices and that premarket notification is necessary to provide reasonable assurance of safety and effectiveness for all three types of single patient use blood lancets.

FDA also does not agree with the comment that the Agency should only review the DHF for a single patient use only blood lancet device to determine whether there exists a reasonable assurance of safety and effectiveness for the device. Under 21 CFR 820.3 a DHF is a compilation of records that describes the design history of a finished device based on the quality system regulations. Although a manufacturer of a legally marketed device is required to keep a DHF for the device’s design control requirements, FDA usually does not review the DHF until postmarket surveillance inspections of a class II device. For single patient use only blood lancet devices, based on the scientific evidence available to the Agency, FDA believes in order for the Agency to determine whether there exists a reasonable assurance of safety and effective for a device, it is necessary for compliance with the special controls to be assessed prior to the device entering the market.

(Comment 11) A comment recommended that FDA create a separate regulatory classification category for “flat, stainless steel” blood lancets in class I.

(Response 11) FDA disagrees that a separate regulatory classification is needed for flat, stainless steel blood lancets in class I. FDA believes that the four subsets of lancets identified in this final order encompass flat, stainless steel blood lancets; that is, a flat, stainless steel blood lancet can be appropriately categorized in any of these four subsets based on its intended use (e.g., single vs. multiple use) and design characteristics (e.g., presence or lack of a sharps injury prevention feature). Furthermore, at this time, FDA finds that the same risks to health (e.g., bloodborne pathogen transmission, local tissue infections, adverse tissue reactions) described herein for blood lancets apply to flat, stainless steel blood lancets. Therefore, FDA finds that a separate categorization for flat stainless steel blood lancets in class I is neither necessary nor appropriate at this time.

(Comment 12) One comment suggested FDA allow a bundling of several devices with the same intended use for a 510(k) submission.

(Response 12) Bundling refers to the inclusion of multiple devices or multiple indications for use for a device in a single premarket submission, including products subject to the device and biologics license application (BLA) authorities, for purposes of review and user fee payment. Multiple devices may include different models within a generic type of device (21 CFR 860.3) or

devices that are of differing generic types. Under the current review process for the Center for Devices and Radiological Health (CDRH), bundling of multiple devices or indications for use are acceptable for 510(k) submission when the devices present scientific and regulatory issues that can most efficiently be addressed during the course of one premarket review (Ref. 10). CDRH will make a determination of acceptable bundling of devices on a case-by-case basis.

(Comment 13) Some comments stated that all multiple use lancets should be class III.

(Response 13) FDA disagrees with this comment. FDA believes the regulatory requirements for blood lancets should be based upon the indications for use of the device and the risk of the device when used as intended. After reviewing the new scientific data supporting the identified risks to health, the Panel recommended that reclassifying subset 3, multiple use for single patient use blood lancets from class I (general controls) to class II (special controls) because multiple use blood lancet devices for single use patients do not present a potential unreasonable risk of illness or injury due to the inherent and significantly increased risk of bloodborne pathogen transmission as compared to multiple patient blood lancets (Ref. 2). As stated above in response to Comment 2 in this section and in the 513(e) Proposed Order (81 FR 11140 at 11148), FDA believes sufficient information exists to establish special controls for mitigating the risks to health for subset 3 (multiple use for single patient use only blood lancets) to provide a reasonable assurance of safety and effectiveness of the device. Because multiple use blood lancets for multiple patient use present a potential unreasonable risk of illness or injury and insufficient information exists to establish special controls for multiple use blood lancets for multiple patient use, FDA reclassified the device into class III.

(Comment 14) Some comments stated that the wording of the subtypes in the 513(e) Proposed Order were unclear and should be revised to distinguish between lancets and lancing medical devices.

(Response 14) FDA understands the concerns of the commenter and is providing in this final order language to explain whether blades are attached to the base in each of the four subsets of blood lancets. The base and blade combine to create the complete lancet. For subset 1 and 2 lancets, the blade is attached to the base with the entire unit being single use. In subset 3 and 4

lancets, single use blades are attached to a multiuse base where the blade is discarded after each use, but each subset has a different labeling requirement. By definition, subsets 1 and 2 blood lancets do not have a blade that can be used independently of the base. Furthermore, FDA provides clear descriptions of special controls that apply to each component for subsets 1, 2, and 3. As discussed at the Panel, multiple use lancets for multiple patients present an unreasonable risk of illness or injury due to the inherent and significantly increased risk of bloodborne pathogen transmission and are therefore reclassified into class III. Therefore, FDA believes that the blood lancet definitions presented during the Panel meeting and provided in the 513(e) Proposed Order are complete and adequate.

(Comment 15) Comment stated that FDA's increase of postmarket surveillance of blood glucose meter accuracy would provide greater impact on mitigating cross-contamination opportunities than reclassification of blood lancets.

(Response 15) Postmarket surveillance of blood glucose meter accuracy is outside the scope of this regulatory action.

IV. The Final Order

Under section 513(e) of the FD&C Act, FDA is adopting its findings as published in the preamble to the 513(e) Proposed Order for these devices (81 FR 11140). FDA is issuing this final order to reclassify single patient use only blood lancets devices from class I (general controls) exempt from premarket notification into class II (special controls) and subject to premarket review.⁴ FDA is reclassifying these devices based on the determination that general controls are insufficient to provide a reasonable assurance of safety and effectiveness for blood lancets and there is sufficient information to establish special controls to provide such assurance for single patient use only blood lancets (subsets 1 to 3). FDA is also establishing special controls for each type of single patient use only blood lancet, which are set forth in § 878.4850(a)(2)(i) through (vi) for single use only blood lancet with an

integral sharps injury prevention feature, § 878.4850(b)(2)(i) through (vi) for single use only blood lancet without an integral sharps injury prevention feature, and § 878.4850(c)(2)(i) through (vii) for multiple use blood lancet for single patient use only. FDA also intends not to enforce compliance with this final order until 1 year after its effective date for manufacturers of blood lancets for single patient use only that are currently marketed for sale prior to the publication of this final order, but do not already have a 510(k) clearance.

FDA is also issuing this final order to reclassify multiple use blood lancets for multiple patient use from class I (general controls) exempt from premarket notification into class III (premarket approval). FDA is reclassifying these devices based on the determination that general controls and special controls together are not sufficient to provide reasonable assurance of safety and effectiveness for this device. In addition, in the absence of an established positive benefit-risk profile, FDA has determined that the risks to health associated with the use of multiple patient use blood lancets identified previously present a potential unreasonable risk of illness or injury. Elsewhere in this issue of the **Federal Register**, FDA has published a final order requiring the filing of a PMA or notice of completion of a PDP for multiple patient use blood lancets.

FDA has also modified the identification in § 878.4800(a) for manual surgical instruments for general use to remove the blood lancet devices from this classification regulation and include them under a separate classification regulation § 878.4850.

V. Premarket Notification Requirement for Single Patient Use Only Blood Lancets

FDA is reclassifying single patient use only blood lancets from class I (general controls) exempt from premarket notification into class II (special controls) and subject to premarket review. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness for the intended uses of all three types of single patient use only blood lancets. Therefore, these three device types are not exempt from premarket notification requirements.

⁴ FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the **Federal Register** Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

FDA cleared several 510(k)s for blood lancets prior to exempting the device types from submission of a premarket notification. These cleared blood lancets, as well as any 510(k)-exempt blood lancets legally offered for sale on or before November 22, 2021, can serve as predicates for substantial equivalence purposes. In order for a single patient use only blood lancet to fall within this classification, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order.

VI. Implementation Strategy

For the three types of blood lancets being reclassified from class I (general controls) to class II (special controls), the special controls identified in this order are effective November 22, 2021. For the fourth type of blood lancet being reclassified from class I to class III, FDA is publishing a final order to require the filing of a PMA or notice of completion of a PDP elsewhere in this issue of the **Federal Register**.

- Blood lancets for single patient use only that have not been offered for sale prior to November 22, 2021, or have been offered for sale but are required to submit a new 510(k) under § 807.81(a)(3): Manufacturers are required to obtain 510(k) clearance before marketing their devices after November 22, 2021. If a manufacturer markets such a device without receiving 510(k) clearance, then FDA would consider taking action against such a manufacturer, under its usual enforcement policies.

- Blood lancets for single patient use only that have been offered for sale prior to November 22, 2021, and do not already have 510(k) clearance: FDA does not intend to enforce compliance with the 510(k) requirement or special controls until November 22, 2022. After that date, if a manufacturer continues to market such a device but does not have a 510(k) clearance or FDA determines that the device is not substantially equivalent or not compliant with the special controls, then FDA would consider taking action against such manufacturer under its usual enforcement policies.

For blood lancets for single patient use that have prior 510(k) clearance, FDA would accept a new 510(k) and would issue a new clearance letter, as appropriate, indicating substantial equivalence and compliance with the special controls. These devices could serve as predicates for new devices. These clearance letters would be made publicly available in FDA's 510(k) database, and compliance with special

controls at the time of clearance would be stated in the publicly available 510(k) Summary posted in this database. Because many blood lancets for single patient use are non-prescription ("over-the-counter") devices, FDA believes that our public database is a transparent tool allowing consumers to confirm that their devices have been submitted under a new 510(k) and demonstrated conformance to the applicable special controls.

The timeframes set forth in this section also apply to compliance with requirements for device labeling (part 801 (21 CFR part 801)), including the UDI labeling requirements (part 801, subpart B), as well as device tracking requirements (21 CFR part 821), device reporting requirements (21 CFR part 803), and GUDID data submission requirements (21 CFR part 830).

VII. Codification of Orders

Prior to the amendments by the Food and Drug Administration Safety and Innovation Act (FDASIA), section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this final order, we are revoking the requirements in 21 CFR 878.4800 related to the classification of blood lancets as class I devices and codifying the reclassification of four types of blood lancets in 21 CFR 878.4850: Single use only blood lancets with an integral sharps injury prevention feature, single use only blood lancets without an integral sharps injury prevention feature, and multiple use blood lancets for single patient use only into class II, and multiple use blood lancet for multiple patient use into class III.

VIII. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

While this final order contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this final order. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 830 have been approved under OMB control number 0910–0720; and the collections of information in 21 CFR parts 800, 801 and 809 have been approved under OMB control number 0910–0485.

The labeling provisions in proposed § 878.4850(a)(2)(vi), (b)(2)(vi), and (c)(2)(vii) are not subject to review by OMB because they do not constitute a "collection of information" under the PRA. Rather, the following labeling: (1) "For use only on a single patient. Discard the entire device after use."; (2) "For use only on a single patient. Disinfect reusable components according to manufacturer's instructions between each use."; (3) "Used lancet blades must be safely discarded after a single use."; (4) "Warning: Not intended for more than one use. Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested."; and (5) "Warning: Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested. The cleaning and disinfection instructions for this device are intended only to reduce the risk of local use site infection; they cannot render this device safe for use for more than one patient." are a "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

X. References

The following references marked with an asterisk (*) are on display at the

Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. *FDA Guidance for Industry and FDA Staff, "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use," September 2020, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/self-monitoring-blood-glucose-test-systems-over-counter-use>.
2. *Executive Summary, Transcript and other meeting material of the June 26, 2013, meeting of the General and Plastic Surgery Devices Panel available at <https://wayback.archive-it.org/7993/20170405193132/https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/ucm349426.htm>.
3. *FDA Guidance for Industry and FDA Staff, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," March 17, 2015, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>.
4. *FDA Guidance for Industry and FDA Staff, "Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use," September 2020, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/blood-glucose-monitoring-test-systems-prescription-point-care-use>.
5. *The World Health Organization (WHO) Guidelines on Drawing Blood: Best Practices in Phlebotomy, Part II, 2, Geneva: World Health Organization, 2010, available at <https://www.ncbi.nlm.nih.gov/books/NBK138665/>.
6. Clinical Laboratory Standards Institute (CLSI), GP42 7th Edition, Collection of Capillary Blood Specimens.
7. *FDA Guidance for Industry and FDA Staff, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," January 21, 2016, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>.

review-sterility-information-premarket-notification-510k-submissions-devices-labeled.

8. *FDA Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process," September 2020, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and-testing-within-a-risk-management-process>.
9. **"Procedures for Class II Device Exemptions from Premarket Notification," Guidance for Industry and CDRH Staff (Class II 510(k) Exemption Guidance), February 19, 1998, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-class-ii-device-exemptions-premarket-notification-guidance-industry-and-cdrh-staff>.
10. *FDA Guidance for Industry and FDA Staff, "Bundling Multiple Devices or Multiple Indications in a Single Submission," June 20, 2007, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bundling-multiple-devices-or-multiple-indications-single-submission>.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Amend § 878.4800 by revising paragraph (a) to read as follows:

§ 878.4800 Manual surgical instrument for general use.

(a) *Identification.* A manual surgical instrument for general use is a nonpowered, hand-held, or hand manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle,

osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892 of this chapter.

* * * * *

■ 3. Add § 878.4850 to subpart E to read as follows:

§ 878.4850 Blood lancets.

(a) *Single use only blood lancet with an integral sharps injury prevention feature—(1) Identification.* A disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base (including an integral sharps injury prevention feature) that is used to puncture the skin to obtain a drop of blood for diagnostic purposes. The integral sharps injury prevention feature allows the device to be used once and then renders it inoperable and incapable of further use.

(2) *Classification.* Class II (special controls). The special controls are:

(i) The design characteristics of the device must ensure that the structure and material composition are consistent with the intended use and must include a sharps injury prevention feature.

(ii) Mechanical performance testing must demonstrate that the device will withstand forces encountered during use and that the integral sharps injury prevention feature will irreversibly disable the device after one use.

(iii) The device must be demonstrated to be biocompatible.

(iv) Sterility testing must demonstrate the sterility of any device component that breaches the skin (e.g., blade).

(v) Labeling must include:

(A) Detailed descriptions, with illustrations, of the proper use of the device and its sharps injury prevention feature.

(B) Handwashing instructions for the user before and after use of the device.

(C) Instructions on preparation (e.g., cleaning, disinfection) of the skin to be pierced.

(D) Instructions for the safe disposal of the device.

(E) Labeling must be appropriate for the intended use environment.

(1) For those devices intended for health care settings, labeling must address the health care facility use of these devices, including how these lancets are to be used with personal protective equipment, such as gloves.

(2) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vi) Labeling must also include the following statements, prominently placed:

(A) “For use only on a single patient. Discard the entire device after use.”

(B) “Warning: Not intended for more than one use. Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested.”

(b) *Single use only blood lancet without an integral sharps injury prevention feature*—(1) *Identification*. A disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) *Classification*. Class II (special controls). The special controls are:

(i) The design characteristics of the device must ensure that the structure and material composition are consistent with the intended use and address the risk of sharp object injuries and bloodborne pathogen transmissions.

(ii) Mechanical performance testing must demonstrate that the device will withstand forces encountered during use.

(iii) The device must be demonstrated to be biocompatible.

(iv) Sterility testing must demonstrate the sterility of any device component that breaches the skin (e.g., blade).

(v) Labeling must include:

(A) Detailed descriptions, with illustrations, of the proper use of the device.

(B) Handwashing instructions for the user before and after use of the device.

(C) Instructions on preparation (e.g., cleaning, disinfection) of the skin to be pierced.

(D) Instructions for the safe disposal of the device.

(E) Labeling must be appropriate for the intended use environment.

(1) For those devices intended for health care settings, labeling must address the health care facility use of these devices, including how these lancets are to be used with personal protective equipment, such as gloves.

(2) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vi) Labeling must also include the following statements, prominently placed:

(A) “For use only on a single patient. Discard the entire device after use.”

(B) “Warning: Not intended for more than one use. Do not use on more than

one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested.”

(c) *Multiple use blood lancet for single patient use only*—(1) *Identification*. A multiple use capable blood lancet intended for use on a single patient that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) *Classification*. Class II (special controls). The special controls are:

(i) The design characteristics of the device must ensure that:

(A) The lancet blade can be changed with every use, either manually or by triggering a blade storage unit to discard the used blade and reload an unused blade into the reusable base; and

(B) The structure and material composition are consistent with the intended use and address the risk of sharp object injuries and bloodborne pathogen transmissions and allow for validated cleaning and disinfection.

(ii) Mechanical performance testing must demonstrate that the device will withstand forces encountered during use.

(iii) The device must be demonstrated to be biocompatible.

(iv) Sterility testing must demonstrate the sterility of any device component that breaches the skin (e.g., blade).

(v) Validation testing must demonstrate that the cleaning and disinfection instructions are adequate to ensure that the reusable lancet base can be cleaned and low level disinfected.

(vi) Labeling must include:

(A) Detailed descriptions, with illustrations, of the proper use of the device.

(B) The Environmental Protection Agency (EPA) registered disinfectant's contact time for disinfectant use.

(C) Handwashing instructions for the user before and after use of the device.

(D) Instructions on preparation (e.g., cleaning, disinfection) of the skin to be pierced.

(E) Instructions on the cleaning and disinfection of the device.

(F) Instructions for the safe disposal of the device.

(G) Instructions for use must address the safe storage of the reusable blood lancet base between uses to minimize contamination or damage and the safe storage and disposal of the refill lancet blades.

(H) Labeling must be appropriate for the intended use environment.

(1) For those devices intended for health care settings, labeling must address the health care facility use of

these devices, including how these lancets are to be used with personal protective equipment, such as gloves.

(2) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vii) Labeling must also include the following statements, prominently placed:

(A) “For use only on a single patient. Disinfect reusable components according to manufacturer's instructions between each use.”

(B) “Used lancet blades must be safely discarded after a single use.”

(C) “Warning: Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested. The cleaning and disinfection instructions for this device are intended only to reduce the risk of local use site infection; they cannot render this device safe for use for more than one patient.”

(d) *Multiple use blood lancet for multiple patient use*—(1) *Identification*. A multiple use capable blood lancet intended for use on multiple patients that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) *Classification*. Class III (premarket approval).

Dated: November 16, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25376 Filed 11–19–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0077]

RIN 1625–AA11

Regulated Navigation Area; Biscayne Bay Causeway Island Slip, Miami Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a Regulated Navigation Area over certain navigable waters of the Biscayne Bay Causeway Island Slip, immediately west of the Coast Guard Base Miami Beach, Miami Beach, FL. This action is necessary to provide for the safety of life and federal property on