confidence interval of greater than or equal to 96 percent.

(4) For devices intended for the quantitative detection of HCV RNA, the following special controls, in addition to those listed in paragraphs (b)(1) and (2) of this section, apply:

(i) Labeling required under § 809.10(b) of this chapter must include a prominent statement that the test is not intended as a diagnostic test to confirm the presence of active HCV infection, when applicable.

(ii) Design verification and validation must include the following:

(A) Detailed documentation of the following analytical performance studies conducted as appropriate to the technology, specimen types tested, and intended use of the device, including but not limited to: LoD, ULoQ and LLoQ. LoD, LLoQ, and linearity studies must demonstrate acceptable device performance with all HCV genotypes detected by the device.

(B) Detailed documentation of clinical performance testing from either:

(*1*) A multisite clinical study with an appropriate number of clinical samples from chronically HCV infected patients in which the results are compared to an FDA-cleared or approved quantitative HCV RNA test, or a comparator that FDA has determined is appropriate. This study must include a sufficient number of HCV positive samples containing an analyte concentration near the LLoQ to describe performance at this level. Clinical samples must cover the full range of the device output and must be consistent with the distribution of these genotypes in the U.S. population. Clinical samples may be supplemented with diluted clinical samples for those viral load concentrations that are not sufficiently covered by natural clinical specimens, or

(*2*) A clinical study with prospectively collected samples demonstrating clinical validity of the device.

(C) Detailed documentation of a qualitative analysis near the lower end of the measuring range demonstrating acceptable performance when used as an aid in diagnosis.

(5) For devices intended for HCV RNA genotyping, in addition to the special controls listed in paragraphs (b)(1) and (2) of this section, design verification and validation must include the following:

(i) Detailed documentation of an analytical performance study demonstrating the LoD for all HCV genotypes detected by the device.

(ii) Detailed documentation, including results, of a multisite clinical study that assesses genotyping accuracy (*i.e.,* the proportion of interpretable results that match with the reference method result) and the genotyping rate (*i.e.,* the proportion of results that were interpretable).

(6) For any nucleic acid-based HCV RNA test intended for Point of Care (PoC) use, the following special controls, in addition to those listed in paragraphs (b)(1) and (2) of this section, apply:

(i) Clinical studies must be conducted at PoC sites.

(ii) Additional labeling must include a brief summary of the instructions for use that are appropriate for use in a PoC environment.

Dated: November 16, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25379 Filed 11–19–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2020–N–1082]

Microbiology Devices; Reclassification of Certain Hepatitis C Virus Antibody Assay Devices, Renamed to Hepatitis C Virus Antibody Tests

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 certain hepatitis C virus (HCV) antibody assay devices intended for the qualitative detection of HCV, postamendments class III devices (product code MZO) into class II (general controls and special controls), subject to premarket notification. FDA is renaming and codifying these devices under the classification regulation named ''hepatitis C virus (HCV) antibody tests.'' FDA is also identifying the special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of these devices.

DATES: This order is effective December 22, 2021.

FOR FURTHER INFORMATION CONTACT: Maria Ines Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3104, Silver Spring, MD 20993–0002, 301–796–7017, *Maria.Garcia@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes 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 classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (general and special controls), and class III (general controls and premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process.[1] Those devices remain in class III and require premarket approval unless, and until, (1) FDA reclassifies the device into class I or II, or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807), subpart E, of the regulations.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide a reasonable assurance of the safety and effectiveness of the device for its intended use.

FDA relies upon ''valid scientific evidence,'' as defined in section 513(a)(3) of the FD&C Act and

[1] HCV antibody assay devices for the qualitative detection of HCV with intended uses outside the scope of the classification under 21 CFR 866.3169 are considered postamendments devices that are subject to classification under section 513(f)(1) of the FD&C Act or, if the relevant requirements are met, under section 513(f)(2) of the FD&C Act.

§ 860.7(c)(2) (21 CFR 860.7(c)(2)), in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the ''valid scientific evidence'' upon which the Agency relies must be publicly available (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c))). Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending premarket approval application (PMA) (see section 520(c) of the FD&C Act).

FDA published a proposed order in the **Federal Register** of April 2, 2020 (85 FR 18490), to reclassify these device types from class III into class II (general controls and special controls), subject to premarket notification. FDA has considered the information available to the Agency, including the deliberations of the March 22, 2018, Microbiology Devices Panel (2018 Panel), and comments from the public docket to determine that there is sufficient information to establish special controls to effectively mitigate the risks to the health identified in section V of the proposed order, and that these special controls, together with general controls, provide a reasonable assurance of safety and effectiveness when applied to certain HCV antibody assay devices intended for the qualitative detection of HCV.

Therefore, in accordance with section 513(f)(3) of the FD&C Act, FDA, on its own initiative, is issuing this final order to reclassify certain HCV antibody assay devices intended for the qualitative detection of HCV from class III to class II (general and special controls).[2]

II. Comments on the Proposed Order

On April 2, 2020, FDA published in the **Federal Register** a proposed order (85 FR 18490) to reclassify certain HCV antibody assay devices intended for the qualitative detection of HCV from class III to class II, subject to premarket notification. The comment period on the proposed order closed on June 1, 2020. In response to the proposed order, FDA received comments from industry, healthcare associations, public health departments, and individual consumers by the close of the comment period, some of which contained one or more comments on one or more issues. We describe and respond to the comments in this section of the document. Certain comments are grouped based on common themes; we grouped similar comments together under the same number and listed them numerically.

The order of response to the commenters is purely for organizational purposes and does not signify the comment's value or importance nor the order in which comments were received. Please note that in some cases we separated different issues discussed by the same commenter and designated them as distinct comments for purposes of our responses.

(Comment 1) FDA received numerous comments in favor of the proposed reclassification of certain HCV antibody assay devices intended for the qualitative detection of HCV from class III to class II with special controls. Commenters stated they believed that special controls, along with general controls, could provide a reasonable assurance of the safety and effectiveness of these devices. In addition, they believed that the decreased regulatory burden resulting from the reclassification could encourage further development of, and provide patients more timely access to, these devices. Overall, there was a general consensus among the commenters that the proposed special controls are necessary and sufficient to mitigate the risks to health of patients presented by these devices and to provide reasonable assurance of the safety and effectiveness of these devices.

(Response 1) Based on the evidence considered, comments received in response to the proposed order and deliberations of the 2018 Panel, FDA agrees with the commenters that reclassification of certain HCV antibody assay devices for the qualitative detection of HCV from class III into class II and that special controls, in addition to general controls, can provide a reasonable assurance of the safety and effectiveness of these devices. In addition, FDA expects that the reclassification of these devices would enable more manufacturers to develop them such that patients would benefit from increased access to safe and effective tests.

(Comment 2) One comment expressed concerns about the proposed reclassification of these devices from class III into class II. The commenter suggested that there was not enough justification to reclassify these devices at this time and asked for clarification on FDA's justification proposing this reclassification. The commenter also asked for clarification on whether a high demand of these devices was a consideration in FDA's proposed reclassification order.

(Response 2) Based on the evidence considered, comments received in response to the proposed order and deliberations of the 2018 Panel, FDA disagrees with this comment and continues to believe that reclassification of these devices is justified for the reasons identified in the proposed order (85 FR 18490). FDA's justification for reclassifying these devices is based on the unanimous recommendation of the 2018 Panel, FDA's accumulated experience with these devices from review submissions, and from published peer-reviewed literature. In addition, FDA believes that the special controls identified in this final order, in addition to the general controls, will provide a reasonable assurance of the safety and effectiveness of these devices.

FDA relies upon ''valid scientific evidence'' as defined in section 513(a)(3) of the FD&C Act and § 860.7(c)(2) in the classification process to determine the level of regulation for devices. FDA believes the standard in section 513(a)(1)(B) of the FD&C Act is met as there is sufficient information to establish special controls, which, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of these devices. While FDA expects that the reclassification of these devices would enable more manufacturers to develop HCV antibody tests such that patients would benefit from increased access to safe and effective tests, this is not a consideration in the Agency's reclassification determination.

(Comment 3) Several commenters had questions about the scope of the proposed reclassification order. Several commenters noted that the proposed reclassification order identified these devices as HCV antibody tests for prescription use and suggested that the reclassification order should also include HCV antibody tests intended for over-the-counter (OTC) use. In addition, one commenter suggested that FDA's reclassification order should also include HCV antigen tests, tests for hepatitis A and hepatitis B, and also that the reclassification should include other specimen types for HCV antibody tests beyond those identified in the proposed order (*e.g.,* urine or saliva).

(Response 3) These comments are beyond the scope of FDA's proposed reclassification order which applies only to HCV antibody tests that have been previously approved by FDA. FDA has not approved any HCV antibody tests intended for OTC use and FDA believes that an HCV antibody tests

[2] 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 the Federal Register's (OFR) interpretation 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.

intended for OTC use would be a new type of device not previously classified based on the criteria at section 513(a)(1) of the FD&C Act and, as a result, such postamendments devices would be automatically classified into class III by operation of section 513(f)(1) of the FD&C Act. FDA believes that an HCV antibody test intended for OTC use may be a good candidate for the De Novo classification process under section 513(f)(2) of the FD&C Act (Refs. 1 and 2). FDA recommends that device manufacturers interested in marketing an HCV antibody test for OTC use submit a Pre-Submission to request FDA feedback on the studies and data that may be necessary to support a De Novo request (Ref. 3).

Similarly, to date, FDA has only approved HCV antibody tests intended for use with human serum or plasma and new specimen types are beyond the scope of this reclassification order.

(Comment 4) Several commenters expressed support of FDA's proposal to rename these devices from ''hepatitis C virus antibody assay devices'' to ''hepatitis C virus (HCV) antibody tests.'' These commenters believed that the new name for these devices made clear that these are diagnostic tests and is consistent with the naming of similar diagnostic devices. Alternatively, several commenters provided suggestions on FDA's proposal to rename these devices to ''hepatitis C virus (HCV) antibody tests.'' One commenter suggested renaming these devices ''HCV serological tests.'' Another commenter suggested renaming these devices ''hepatitis C virus (HCV) antibody test devices.''

(Response 4) FDA believes that the new identification of these devices as ''hepatitis C virus (HCV) antibody tests'' is both understandable to consumers and industry and is consistent with the naming of similar diagnostic devices.

FDA disagrees with those commenters that proposed renaming these devices ''HCV serological tests'' or ''hepatitis C virus (HCV) antibody test devices'' as FDA believes that the identification of these devices as ''hepatitis C virus (HCV) antibody tests'' adequately identifies the types of devices that would be affected by this reclassification action and is clear and consistent with the naming of similar diagnostic devices.

(Comment 5) One commenter suggested that HCV antibody tests could be classified in part 866 (21 CFR part 866) after ''Hepatitis A virus (HAV) serological reagents'' which are currently classified under 21 CFR 866.3310.

(Response 5) FDA disagrees with this comment because FDA believes that the classification of HCV antibody tests under § 866.3169 (21 CFR 866.3169) is appropriate. In addition, FDA has proposed to reclassify nucleic acid-based HCV ribonucleic acid (RNA) devices intended for the qualitative or quantitative detection or genotyping of HCV RNA under § 866.3170 (21 CFR 866.3170) (85 FR 18483). The classification of HCV antibody tests in § 866.3169 would allow for these devices to be located next to nucleic acid-based HCV RNA tests in the Code of Federal Regulations (CFR).

(Comment 6) One commenter requested that FDA state the time that it generally takes for FDA to review 510(k) submissions and PMA applications.

(Response 6) Review times for a particular device may vary but the FD&C Act requires manufacturers to submit a 510(k) to FDA at least 90 days before introducing, or before delivering for introduction, a device into interstate commerce (see section 510(k) of the FD&C Act). For comparison, FDA has 180 days to review a PMA starting on the date an application is accepted for filing (see section 515(d) of the FD&C Act (21 U.S.C. 360e(d)) and 21 CFR 814.40).

(Comment 7) One comment indicated a patient who was diagnosed with hepatitis was successfully treated. Another comment requested that FDA consider reducing the prices of HCV antibody tests as a result of their reclassification.

(Response 7) Each of these comments are outside the scope of this reclassification action.

(Comment 8) Several comments expressed general support of the special controls identified in the proposed order and believed they would provide a reasonable assurance of safety and effectiveness of these devices. In addition, several commenters suggested that FDA revise the special controls to include a requirement that the labeling identify where and when these devices may be used consistent with infection control standards and FDA guidance documents for infection control. Additionally, it was suggested that the labeling specify the special populations of patients for which test performance may be affected.

(Response 8) FDA continues to believe that the special controls identified in the proposed order and finalized in this final order are sufficient to provide a reasonable assurance of safety and effectiveness of HCV antibody tests.

FDA disagrees that a further level of specificity is necessary for inclusion within the special controls to provide a reasonable assurance of safety and effectiveness for these devices and wants to ensure that the special controls remain appropriate and applicable to provide a reasonable assurance of safety and effectiveness for these devices over time. Further, performance of these devices may evolve over time for special populations and any special populations for which performance of these devices may be affected are required to be included in the labeling for these devices by the special controls (see § 866.3169(b)(1)(ii)(A)).

III. The Final Order

Based on the information discussed in the preamble to the proposed order (85 FR 18490), the comments received for the proposed order, the 2018 Panel deliberations (Ref. 4), and FDA's experiences over the years in reviewing these device types, FDA concludes that special controls, in conjunction with general controls, will provide a reasonable assurance of the safety and effectiveness of HCV antibody tests. FDA is adopting its findings under section 513(f)(3) of the FD&C Act, as published in the preamble to the proposed order. FDA is issuing this final order to reclassify HCV antibody tests intended for the qualitative detection of HCV from class III to class II, and establishing special controls by revising part 866. In this final order, the Agency has identified the special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls, provide a reasonable assurance of the safety and effectiveness of these devices.

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 a reasonable assurance of the safety and effectiveness of HCV antibody tests. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market a new HCV antibody assay device must submit to FDA a premarket notification, obtain clearance, and demonstrate compliance with the special controls included in this final order, prior to marketing the device.

These devices are assigned the generic name ''HCV antibody tests'' and identified as in vitro diagnostic devices intended for use with human serum,

plasma, or other matrices as a prescription device that aids in the diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection. The test is not intended for screening blood, plasma, cell, or tissue donors.

Under this final order, HCV antibody tests are identified as prescription use only devices and as such, HCV antibody tests must satisfy prescription labeling requirements for in vitro diagnostic products (see 21 CFR 809.10(a)(4) and (b)(5)(ii)). Under 21 CFR 807.81, the device continues to be subject to 510(k) requirements.

IV. Codification of Orders

Prior to the amendments in the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) (FDASIA), section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e), as amended by FDASIA, requires FDA to issue final orders rather than regulations, it also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the 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), as amended by FDASIA, in this final order, we are proposing to codify the classification of hepatitis c virus antibody tests in the new § 866.3169, under which HCV antibody tests would be reclassified into class II.

V. 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.

VI. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved FDA collections. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

VII. References

The following references 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.* 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. ''De Novo Classification Process (Evaluation of Automatic Class III Designation)—Guidance for Industry and Food and Drug Administration Staff,'' issued October 30, 2017 (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/de-novo-classification-process-evaluation-automatic-class-iii-designation*).
2. ''Acceptance Review for De Novo Classification Requests—Guidance for Industry and Food and Drug Administration Staff,'' issued September 9, 2019 (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests*).
3. ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program—Guidance for Industry and Food and Drug Administration Staff,'' issued May 7, 2019 (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program*).
4. Transcript of the FDA Microbiology Devices Panel Meeting, March 22, 2018 (available at *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/UCM630139.pdf*).

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, 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 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

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

■ 2. Add § 866.3169 to subpart D to read as follows:

§ 866.3169 Hepatitis C virus antibody tests.

(a) *Identification.* A hepatitis C virus (HCV) antibody test is identified as an in vitro diagnostic device intended for use with human serum, plasma, or other matrices as a prescription device that aids in the diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection. The test is not intended for screening blood, plasma, cell, or tissue donors.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The labeling required under § 809.10(b) of this chapter must include:

(i) A prominent statement that the test is not intended for the screening of blood, plasma, and cell or tissue donors.

(ii) Limitations, which must be updated to reflect current clinical practice and disease presentation and management. The limitations must include, but are not limited to, statements that indicate:

(A) When appropriate, the performance characteristics of the test have not been established in populations of immunocompromised or immunosuppressed patients or, other special populations where test performance may be affected.

(B) The detection of HCV antibodies indicates a present or past infection with hepatitis C virus, but does not differentiate between acute, chronic, or resolved infection.

(C) The specimen types for which the device has been cleared, and that use of the test with specimen types other than those specifically cleared for this device may result in inaccurate test results.

(D) Test results are to be interpreted by qualified licensed healthcare professionals in conjunction with the individual's clinical presentation, history, and other laboratory results.

(E) A non-reactive test result may occur early during acute infection, prior to development of a host antibody response to infection, or when analyte levels are below the limit of detection of the test.

(iii) A detailed explanation of the principles of operation and procedures for performing the test.

(2) Design verification and validation must include the following:

(i) A detailed device description, including all parts that make up the device, ancillary reagents required but not provided, an explanation of the device methodology, and design of the antigen(s) and capture antibody(ies)

sequences, rationale for the selected epitope(s), degree of amino acid sequence conservation of the target, and the design and nature of all primary, secondary, and subsequent standards used for calibration.

(ii) Documentation and characterization (*e.g.,* supplier, determination of identity, and stability) of all critical reagents (including description of the antigen(s) and capture antibody(ies)), and protocols for maintaining product integrity throughout its labeled shelf life.

(iii) Risk analysis and management strategies, such as Failure Modes Effects Analysis and/or Hazard Analysis and Critical Control Points summaries and their impact on test performance.

(iv) Final release criteria to be used for manufactured test lots with appropriate evidence that lots released at the extremes of the specifications will meet the claimed analytical and clinical performance characteristics as well as the stability claims.

(v) Stability studies for reagents must include documentation of an assessment of real-time stability for multiple reagent lots using the indicated specimen types and must use acceptance criteria that ensure that analytical and clinical performance characteristics are met when stability is assigned based on the extremes of the acceptance range.

(vi) All stability protocols, including acceptance criteria.

(vii) Final release test results for each lot used in clinical studies.

(viii) Multisite reproducibility study that includes the testing of three independent production lots.

(ix) Analytical performance studies and results for determining the limit of blank (LoB), limit of detection (LoD), cutoff, precision (reproducibility) including lot-to-lot and/or instrument-to-instrument precision, interference, cross reactivity, carryover, hook effect, seroconversion panel testing, matrix equivalency, specimen stability, reagent stability, and cross-genotype antibody detection sensitivity, when appropriate.

(x) Analytical sensitivity of the test is the same or better than that of other cleared or approved tests.

(xi) Detailed documentation of clinical performance testing from a multisite clinical study. Performance must be analyzed relative to an FDA cleared or approved HCV antibody test, or a comparator that FDA has determined is appropriate. This study must be conducted using appropriate patient samples, with an acceptable number of HCV positive and negative samples in applicable risk categories. Additional relevant patient groups must be validated as appropriate. The samples may be a combination of fresh and repository samples, sourced from geographically diverse areas. The study designs, including number of samples tested, must be sufficient to meet the following criteria:

(A) Clinical sensitivity of the test must have a lower bound of the 95 percent confidence interval of greater than or equal to 95 percent.

(B) Clinical specificity of the test must have a lower bound of the 95 percent confidence interval of greater than or equal to 96 percent.

(3) For any HCV antibody test intended for Point of Care (PoC) use, the following special controls, in addition to those listed in paragraphs (b)(1) and (2) of this section, apply:

(i) Clinical studies must be conducted at PoC sites.

(ii) Additional labeling must include a brief summary of the instructions for use that are appropriate for use in a PoC environment.

Dated: November 16, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25374 Filed 11–19–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2016–M–0035]

Effective Date of Requirement for Premarket Approval for Blood Lancets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a final order to require the filing of a premarket approval application (PMA) or notice of completion of a product development protocol (PDP) following the reclassification of multiple use blood lancets for multiple patient use from class I to class III.

DATES: This order is effective on November 22, 2021.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993–0002, 301–796–6527, *rebecca.nipper@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes 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)(1) of the FD&C Act, devices that were in commercial distribution before the enactment of the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), May 28, 1976 (generally referred to as ''preamendments devices''), are classified after FDA: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

A preamendments device that has been classified into class III and devices found substantially equivalent by means of premarket notification (510(k)) procedures to such a preamendments device or to a device within that type (both the preamendments and substantially equivalent devices are referred to as preamendments class III devices) may be marketed without submission of a PMA until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval. Section 515(b)(1) of the FD&C Act directs FDA to issue an order requiring premarket approval for a preamendments class III device.

Section 515(f) of the FD&C Act provides an alternative pathway for meeting the premarket approval requirement. Under section 515(f), manufacturers may meet the premarket approval requirement if they file a notice of completion of a PDP approved under section 515(f)(4) of the FD&C Act and FDA declares the PDP completed under section 515(f)(6)(B) of the FD&C Act. Accordingly, the manufacturer of a preamendments class III device may comply with a call for PMAs by filing a PMA or a notice of completion of a PDP. In practice, however, the option of filing a notice of completion of a PDP has rarely been used. For simplicity, although the PDP option remains available to manufacturers in response to a final order under section 515(b) of