DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2013–N–1518]

Cardiovascular Devices; Reclassification of Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Cardiopulmonary and Circulatory Bypass; Effective Date of Requirement for Premarket Approval for Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Temporary Ventricular Support

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed administrative order to reclassify nonroller-type cardiopulmonary bypass blood pump devices, when used for cardiopulmonary and circulatory bypass, a preamendments class III device, into class II (special controls) and subject to premarket notification based on new information. FDA is also proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for nonroller-type cardiopulmonary bypass blood pump devices for temporary ventricular support. The Agency is also summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements when used for temporary ventricular support. In addition, FDA is announcing the opportunity for interested persons to request that the Agency change the classification of any of the devices mentioned in this document based on new information. This action implements certain statutory requirements.

DATES: Submit either electronic or written comments on this proposed order by April 7, 2014. FDA intends that, if a final order based on this proposed order is issued, anyone who wishes to continue to market nonroller-type cardiopulmonary bypass blood pump devices for temporary ventricular support will need to file a PMA or a notice of completion of a PDP within 90 days of the effective date of the final order. See section XVII of this document for the proposed effective date of any final order based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–1518, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–1518 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Angela Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1666, Silver Spring, MD 20993, 301–796–6380, *angela.krueger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), 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 of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, 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.

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) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or 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. The Agency 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).

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 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 or until the device is subsequently reclassified into class I or class II.

Although, under the FD&C Act, the manufacturer of a class III preamendments device may respond to the call for PMAs by filing a PMA or a notice of completion of a PDP, in practice, the option of filing a notice of completion of a PDP has not been used. For simplicity, although corresponding

requirements for PDPs remain available to manufacturers in response to a final order under section 515(b) of the FD&C Act, this document will refer only to the requirement for the filing and receiving approval of a PMA.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended section 513(e) of the FD&C Act, changing the process for reclassifying a device from rulemaking to an administrative order. Section 608(b) of FDASIA (126 Stat. 1056) amended section 515(b) of the FD&C Act, changing the process for requiring premarket approval for a preamendments class III device from rulemaking to an administrative order.

A. Reclassification

FDA is publishing this document to propose the reclassification of nonroller-type cardiopulmonary bypass blood pump devices for cardiopulmonary and circulatory bypass from class III to class II.

Section 513(e) of the FD&C Act governs reclassification of classified preamendments devices. This section provides that FDA may, by administrative order, reclassify a device based upon ''new information.'' FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify a preamendments device. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland-Rantos Co.* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see *Bell,* 366 F.2d at 181; *Ethicon, Inc.* v. *FDA,* 762 F.Supp. 382, 388–391 (D.D.C. 1991)), or in light of changes in ''medical science'' (*Upjohn,* 422 F.2d at 951). Whether data before the Agency are old or new data, the ''new information'' to support reclassification under section 513(e) must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the FD&C Act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). (See, e.g., *General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Association* v. *FDA,* 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1986).)

FDA relies upon ''valid scientific evidence'' 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. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).) Section 520(h)(4) of the FD&C Act, added by FDAMA, provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This can include information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device but does not include descriptions of methods of manufacture or product composition and other trade secrets.

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 has held a meeting of a device classification panel described in section 513(b) of the FD&C Act with respect to nonroller-type cardiopulmonary bypass blood pump devices, and therefore, has met this requirement under section 515(e) of the FD&C Act.

FDAMA added section 510(m) to the FD&C Act. Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

B. Requirement for Premarket Approval Application

FDA is proposing to require PMAs for nonroller-type cardiopulmonary bypass blood pump devices for temporary ventricular support.

Section 515(b)(1) of the FD&C Act sets forth the process for issuing a final order requiring PMAs. Specifically, prior to the issuance of a final order requiring premarket approval for a preamendments class III 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 from all affected stakeholders, including patients, payors, and providers. The meeting of the device classification panel described in section 513(b) of the FD&C Act with respect to nonroller-type cardiopulmonary bypass blood pump devices satisfies this requirement under section 515(b)(1) of the FD&C Act.

Section 515(b)(2) of the FD&C Act provides that a proposed order to require premarket approval shall contain: (1) The proposed order, (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device, (3) an opportunity for the submission of comments on the proposed order and the proposed findings, and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(3) of the FD&C Act provides that FDA shall, after the close of the comment period on the proposed order, consideration of any comments received, and a meeting of a device classification panel described in section 513(b) of the FD&C Act, issue a final order to require premarket approval or publish a document terminating the proceeding together with the reasons for such termination. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the FD&C Act, unless the reason for termination is that the device is a banned device under section 516 of the FD&C Act (21 U.S.C. 360f).

Under section 501(f) of the FD&C Act (21 U.S.C. 351(f)), a preamendments class III device may be commercially distributed without a PMA until 90 days after FDA issues a final order (or a final rule under section 515(b) of the FD&C Act if issued prior to the enactment of FDASIA) requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the FD&C Act, whichever is later. For nonroller-type cardiopulmonary bypass blood pump devices, the preamendments class III devices that are the subject of this proposal, the later of these two time periods is the 90-day period. Since these devices were classified in 1980, the 30-month period has expired (45 FR 7959, February 5, 1980). Therefore, if the proposal to require premarket approval for nonroller-type cardiopulmonary bypass blood pump devices for

temporary ventricular support is finalized, section 501(f)(2)(B) of the FD&C Act requires that a PMA for such device be filed within 90 days of the date of issuance of the final order. If a PMA is not filed for such devices within 90 days after the issuance of a final order, the device would be deemed adulterated under section 501(f) of the FD&C Act.

Also, a preamendments device subject to the order process under section 515(b) of the FD&C Act is not required to have an approved investigational device exemption (IDE) (see part 812 (21 CFR part 812)) contemporaneous with its interstate distribution until the date identified by FDA in the final order requiring the filing of a PMA for the device. At that time, an IDE is required only if a PMA has not been filed. If the manufacturer, importer, or other sponsor of the device submits an IDE application and FDA approves it, the device may be distributed for investigational use. If a PMA is not filed by the later of the two dates, and the device is not distributed for investigational use under an IDE, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the FD&C Act, and subject to seizure and condemnation under section 304 of the FD&C Act (21 U.S.C. 334) if its distribution continues. Other enforcement actions include, but are not limited to, the following: Shipment of devices in interstate commerce will be subject to injunction under section 302 of the FD&C Act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the FD&C Act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA has been filed and may determine that such a request is appropriate for the class III devices that are the subject of this proposed order, if finalized.

In accordance with section 515(b) of the FD&C Act, interested persons are being offered the opportunity to request reclassification of nonroller-type cardiopulmonary bypass blood pump devices for temporary ventricular support.

II. Device Description

A nonroller-type blood pump, also referred to as a nonroller-pump (NRP), is a prescription device that uses a method other than revolving rollers to pump blood. While the technologies utilized by NRPs which have been reviewed by the Agency to date include: (1) Centrifugal pumps and (2) catheter-based axial pumps, additional methods for blood propulsion can be anticipated in future devices.

To further delineate types of NRP devices and their intended uses, FDA proposes to rename the devices in this regulation for purposes of consistency and clarity. The term ''NRP Devices for Temporary Cardiopulmonary Bypass'' will be used to designate blood pumps that use nonroller pump technology temporarily (i.e. <6 hours) to propel blood through a cardiopulmonary bypass circuit. The term ''NRP Devices for Temporary Circulatory Bypass'' will be used to designate blood pumps that utilize nonroller pump technology to provide temporary (i.e. <6 hours) circulatory bypass around a planned surgical disruption of the arterial and venous great vessels (i.e. aorta and vena cavae). The term ''NRP Devices for Temporary Ventricular Support'' will be used to designate blood pumps that use nonroller pump technology (e.g. axial or centrifugal flow pumps) to provide temporary (i.e. <6 hours) support of ventricular function resulting from ongoing or anticipated episodes of immediately reversible myocardial dysfunction.

A. NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass

NRP devices in current use for temporary cardiopulmonary and circulatory bypass rely primarily upon centrifugal pump technology that utilizes a rotor to impart energy to the blood in an extracorporeal circuit through centrifugal forces. These pumps house an impeller, magnet, and housing bottom that fit into a drive unit. The motor drive unit holds the disposable blood pump and drives the rotor inside the blood pump with a magnet. These types of pumps have been used as part of an extracorporeal circuit, external to the body and in combination with an oxygenator, to provide cardiopulmonary support for periods lasting less than 6 hours. Additionally, centrifugal pumps can be used in isolation, external to the body but without an oxygenator, to provide temporary circulatory bypass around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava. Although all currently available devices rely on centrifugal forces to propel blood through these circuits, additional methods for blood propulsion can be anticipated in future devices. For all these future devices, the technology to propel blood as or more efficiently (i.e. adequate volume and with minimal trauma) compared with current technology will be essential in the evaluation for marketing authorization.

B. NRP Devices for Temporary Ventricular Support

NRP devices that pump blood for the purpose of full or partial temporary (i.e. <6 hours) ventricular support may be divided into two broad categories: (1) Those where the temporary NRP device resides within the circulation, and 2) those where the temporary NRP device resides outside the circulation. NRP devices used for temporary ventricular support also typically require percutaneous placement of either catheters (which contain the pump device), or access cannulae. Either or both of these may be required to reside in and/or traverse one or more elements of the circulation (great vessels, valves, septa). Examples include catheter-based microaxial-type pumps comprising a pump motor, cannula, and catheter that connect to a console. Catheter-based microaxial-type pumps are not currently designed to be used with an oxygenator but are temporarily implanted within the heart or vasculature to provide cardiac support by supplementing the function of one or both ventricles, restoring forward flow, and/or allowing the ventricle to rest and repair by decreasing the work and energy demands secondary to ventricular unloading. Centrifugal pump circuits, where the NRP resides outside of the body, have also been used for this purpose following percutaneous placement of inflow and outflow cannulas into the appropriate chambers and vessels. Future development of other pump and cannula technologies to be used for the purpose of temporary ventricular support is anticipated.

III. Regulatory History of the Device

As discussed in the preamble to the proposed rule to classify these devices into class III (44 FR 13409, March 9, 1979), the Cardiovascular Device Classification Panel (the 1979 Panel) recommended that nonroller-type cardiopulmonary bypass blood pumps be classified into class III because the device is life supporting and is potentially hazardous to life or health even when properly used. The 1979 Panel noted that the device is attached directly to the cardiopulmonary bypass circuit and is used in a clinical environment where excessive leakage current can be a serious hazard. The 1979 Panel further noted that the device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, or maintained. The 1979 Panel indicated that general controls alone would not

provide sufficient control over the performance characteristics of the device. Additionally, a performance standard would not provide reasonable assurance of the safety and effectiveness of the device; the Panel noted further that there was not sufficient information to establish a standard to provide such assurance. Consequently, the 1979 Panel believed that premarket approval was necessary to assure the safety and effectiveness of the device. In 1980, FDA classified nonroller-type cardiopulmonary bypass blood pumps into class III after receiving no comments on the proposed rule (45 FR 7959, February 5, 1980).

In 1987, FDA published a clarification by inserting language in the codified language stating that no effective date had been established for the requirement for premarket approval for nonroller-type cardiopulmonary bypass blood pumps (52 FR 17732, May 11, 1987).

On July 6, 1993, FDA published a proposed rule to establish an effective date of requirement for premarket approval (i.e. call for PMAs) for nonroller-type cardiopulmonary bypass blood pumps, and provided an opportunity to request a change in classification in the form of a reclassification petition (58 FR 36290). On July 21, 1993, FDA received a reclassification petition from manufacturers of these devices recommending reclassification to class II (special controls). On August 21, 1995, FDA convened the Circulatory System Devices Classification Panel (the 1995 Panel) to review the proposed reclassification and proposed special controls for nonroller-type cardiopulmonary blood pumps for use in cardiopulmonary bypass circuits for periods of up to 6 hours. Reclassification to class II with special controls was supported by the 1995 Panel for nonroller-type cardiopulmonary blood pumps for use in cardiopulmonary bypass circuits for periods of up to 6 hours. FDA did not issue a final regulation codifying the proposed reclassification. In 2004, the July 6, 1993, proposed rule (58 FR 36290) was withdrawn because the proposed rule was no longer considered a viable candidate for final action, due to the length of time that had elapsed since the proposed rule was issued (69 FR 68831, November 26, 2004).

In 2009, FDA published an order for the submission of information on nonroller-type cardiopulmonary bypass blood pumps by August 7, 2009 (74 FR 16214, April 9, 2009). FDA received seven responses to that order from device manufacturers. All manufacturers recommended that nonroller-type cardiopulmonary bypass blood pumps be reclassified to class II. The manufacturers stated that data available in the clinical literature, preclinical and clinical testing, additional knowledge and information regarding the clinical use of the devices, and the overall number of marketed devices provide reasonable assurance of safety and effectiveness of these devices.

As explained further in sections VII and XI of this document, a meeting of the Circulatory System Devices Panel (the 2012 Panel) took place December 6, 2012, to discuss whether nonroller-type cardiopulmonary bypass blood pump devices should be reclassified or remain in class III. The 2012 Panel recommended that nonroller-type cardiopulmonary bypass blood pump devices for cardiopulmonary and circulatory bypass be reclassified to class II with special controls, and nonroller-type cardiopulmonary bypass blood pump devices for temporary ventricular support remain in class III because the device is life-supporting and there was insufficient information to establish special controls for this use. FDA is not aware of new information that would provide a basis for a different recommendation or findings.

IV. Proposed Reclassification

FDA is proposing that NRP devices used to propel blood within temporary (i.e. less than 6 hours) extracorporeal cardiopulmonary and circulatory bypass circuits be reclassified from class III to class II. In this proposed order, the Agency has identified special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls applicable to the devices, would provide reasonable assurance of their safety and effectiveness. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and 21 CFR 860.130, based on new information with respect to the devices, and taking into account the public health benefit of the use of the device and the nature and known incidence of the risk of the device, FDA, on its own initiative, is proposing to reclassify NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass into class II. FDA believes that this new information is sufficient to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in the next section, and that these special controls, together with general controls, will provide a reasonable assurance of safety and effectiveness for NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass.

Section 510(m) of the FD&C Act authorizes the Agency to exempt class II devices from premarket notification (510(k)) submission. FDA has considered NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass in accordance with the reserved criteria set forth in section 513(a) of the FD&C Act and decided that the device does require premarket notification. Therefore, the Agency does not intend to exempt this proposed class II device from premarket notification (510(k)) submission.

Because NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass can currently be marketed after receiving clearance of an application for premarket notification, and FDA is proposing to reclassify these devices as class II requiring clearance of an application for premarket notification, this order, if finalized, will not require a new premarket submission for NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass.

V. Risks to Health

After considering available information, including the recommendations of the advisory committees (panels) for the classification of these devices, FDA has evaluated the risks to health associated with the use of NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass and determined that the following risks to health are associated with their use:

- *Alteration in blood composition:* It is essential that the flow characteristics, heat generated by the pump within the extracorporeal circuit, materials, surface finish, and/or cleanliness of the device do not promote blood component trauma. Resulting complications could include bleeding, hemolysis, thrombus formation, and/or complement activation. Improper mechanical design of the device can also result in such complications.
- *Inadequate tissue perfusion:* If the design of the pump is improper, or the pump is unable to pump blood adequately through a cardiopulmonary bypass circuit, inadequate organ perfusion can result. Limb ischemia, access vessel injury, or dissection resulting in ischemia can result from peripheral cardiopulmonary bypass access.
- *Embolism:* Improper design of the device may cause the generation of

gaseous, particular, or thrombotic emboli, which can result in debilitating or fatal complications such as stroke, peripheral emboli, or death.

- *Use beyond intended duration:* Use of the pump beyond the intended duration can result in more frequent and severe adverse effects.
- *Fluid leakage:* If the structural integrity of the pump is compromised, fluid leakage may result.
- *Adverse tissue reaction:* Inadequate compatibility of the patient-contacting materials of the device may cause physical damage to the blood components, or may cause an adverse immunological or allergic reaction in a patient.
- *Infection:* Defects in the design or construction of the device preventing adequate cleaning and/or sterilization can allow pathogenic organisms to be introduced and can cause an infection in a patient.

VI. Summary of Reasons for Reclassification

If properly manufactured and used as intended, NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass can provide a treatment option for patients when used for cardiopulmonary bypass by providing propulsion of blood through cardiopulmonary bypass circuits or when used for circulatory bypass by allowing planned surgical disruptions of the circulation to avoid distal organ ischemia or venous hypertension. FDA believes NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass should be reclassified from class III to class II because special controls, in addition to general controls, can be established to provide reasonable assurance of the safety and effectiveness of the device, and because general controls themselves are insufficient to provide reasonable assurance of its safety and effectiveness. In addition, there is now adequate effectiveness information sufficient to establish special controls to provide such assurance. FDA believes that the risks to health identified in section V associated with NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass can be mitigated with general and special controls. FDA has identified the risks to health in the table that follows, and the special controls to mitigate these identified risks.

Identified risk	Mitigation measures
Alteration in Blood Composition	Nonclinical Performance/Bench Testing Labeling.
Inadequate Tissue Perfusion	Nonclinical Performance/Bench Testing Labeling.
Embolism	Nonclinical Performance/Bench Testing Labeling.
Duration of Use	Labeling.
Fluid Leakage	Nonclinical Performance/Bench Testing.
Adverse Tissue Reaction	Biocompatibility.
Infection	Sterility and Shelf-Life Testing.

VII. Summary of Data Upon Which the Reclassification Is Based

Since the time of the 1979 Panel recommendation, sufficient evidence has been developed to support a reclassification of NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass to class II with special controls. FDA has been reviewing these devices for many years and their risks are well known. FDA conducted a comprehensive review of available literature for NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass. FDA's review found 18 studies, including 1 randomized controlled study (RCT), 1 meta-analysis, 4 cohort studies, and 12 case studies, which provided consistent evidence of the safety and effectiveness of NRP Devices for Temporary Cardiopulmonary Bypass. Further, FDA's review found 23 studies related to NRP Devices for Temporary Circulatory Bypass, including studies related to both venovenous bypass and aortic procedures, which provided consistent evidence of the safety and effectiveness of NRP Devices for Temporary Circulatory Bypass.

The literature data support that the overall complication rates for NRP Devices for Temporary Cardiopulmonary Bypass is similar to that of another class II device type, roller-type cardiopulmonary bypass blood pumps (21 CFR 870.4370). For example, a meta-analysis of 18 RCTs by Saczkowski et al. obtained pooled estimates for a number of clinical outcome measures (Ref. 1). This meta-analysis represented 1,868 adult patients undergoing cardiopulmonary bypass using either a roller pump (907) or a centrifugal pump (961), undergoing predominantly coronary bypass graft surgery (87 percent and 88 percent, respectively). Patients that underwent a cardiopulmonary bypass procedure either using NRPs or roller pumps had no differences in mortality (n = 1,080, odds ratio (OR): 1.05, 95 percent confidence interval (CI): 0.58, 1.88), bleeding (mean difference: −10.26 mL, 95 percent CI: −54.28, 33.75), and blood transfusion (OR: 1.11, 95 percent CI: 0.64, 1.92) at the end of cardiopulmonary bypass or 1 day after the procedure. Similarly, no statistically significant differences were found on other safety endpoints reported (postoperative atrial fibrillation, cerebral damage, platelet count, hemoglobin, white blood cell count, hematocrit, intensive care unit length of stay, hospital length of stay, and neurologic outcomes). Additionally, Parolari et al. published a cohort study of 4,000 patients that demonstrated that patients that had cardiopulmonary bypass with either a centrifugal pump or a roller pump had the same in-hospital mortality (2 percent) (Ref. 2). Multivariate results showed that patients who underwent cardiopulmonary bypass with the centrifugal pump had a reduction in perioperative permanent neurological deficit and perioperative coma of 43 percent and 54 percent, respectively, compared to those patients that had a circuit utilizing a roller pump ($p < 0.05$).

The literature data also support the effectiveness of NRP Devices for Temporary Cardiopulmonary Bypass. Based on FDA's analysis, the most common indicators of effectiveness were length of stay at the hospital, length of stay in the intensive care unit (ICU), and duration of intubation. In Saczkowski's meta-analysis (Ref. 1), no statistically significant differences were found between the NRPs and roller pumps' pooled estimates in intensive care unit length of stay and hospital length of stay. Intubation time among these patients ranged from 8 hours to more than 1 day. Similarly, Zirbel et al. did not find significant differences in a small cohort study in the hospital and ICU length of stay and intubation time among patients on cardiopulmonary bypass with a selected centrifugal pump as compared to those on a roller pump (Ref. 3).

The safety and effectiveness of NRPs Devices for Temporary Circulatory Bypass during surgical procedures on

the descending thoracic or thoracoabdominal aorta have been reported by numerous authors (Refs. 4–9). These devices have supplanted the use of passive shunts (e.g., Gott shunt) due to their ability to provide more reliable and controllable flow to the distal aorta and the organs it perfuses during planned proximal surgical disruptions. In general, centrifugal pumps used for temporary circulatory bypass in these procedures have provided additional margins of safety by allowing for completion of these procedures in a less rushed fashion and without full cardiopulmonary bypass (and full heparinization). Additionally, use of NRPs has been shown to decrease the incidence of distal organ malperfusion and paraplegia, especially during prolonged cross-clamp intervals (>30–45 minutes) and reduce transfusion requirements. Use of NRPs for circulatory bypass has not been associated with significant adverse events related to the centrifugal pump such as thrombosis, thromboembolism, or cannulation-related injuries.

The literature data outlined in this document support a conclusion of reasonable evidence for the safety and effectiveness of cardiopulmonary and circulatory bypass blood pump devices. In addition, bench studies designed to demonstrate the devices' ability to function as intended have been well characterized.

FDA's presentation to the 2012 Panel included a summary of the available safety and effectiveness information for NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass, including identified risks to health drawn from adverse event reports from FDA's Manufacturer and User Facility Device Experience (MAUDE) database and available literature. Based on the available scientific literature, which supports that use of NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass may be beneficial for patients requiring cardiopulmonary or circulatory bypass, FDA recommended to the 2012 Panel that NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass be reclassified to class II (special controls). The 2012 Panel agreed with FDA's conclusion that the available scientific evidence is adequate to support the safety and effectiveness of NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass.

The 2012 Panel also acknowledged that NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass are life-supporting devices and provided the following rationale for recommending that NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass be reclassified to class II: (1) The available scientific evidence supports an adequate assurance of safety and effectiveness for the device; (2) there is evidence that the device provides hemodynamic support; and (3) the recommended special controls will mitigate the health risks associated with the device.

The 2012 Panel agreed with the identified risks to health presented at the meeting but also recommended that limb ischemia, access vessel injury, and dissection resulting in ischemia related to cardiopulmonary bypass access be considered in the risks to health. FDA agrees with the 2012 Panel's recommendation and modified the risks to health accordingly as outlined in section V of this document. Specifically, the definition of ''inadequate tissue perfusion'' was expanded to include these events. The 2012 Panel also agreed with FDA's proposed special controls outlined in section VIII of this document. The 2012 Panel transcript and other meeting materials are available on FDA's Web site (Ref. 10).

VIII. Proposed Special Controls

FDA believes that the following special controls, together with general controls, are sufficient to mitigate the risks to health described in section V of this document:

1. Nonclinical performance testing must provide a reasonable assurance of safety and effectiveness with respect to the operating parameters, dynamic blood damage, heat generation, air entrapment, mechanical integrity, and durability/reliability to perform as intended over the intended duration of use;

2. The device must be demonstrated to be biocompatible;

3. Sterility and shelf-life testing must demonstrate the sterility of patient-contacting components and the shelf-life of these components; and

4. Labeling must include information regarding the duration of use and a detailed summary of the device- and procedure-related complications pertinent to use of the device.

NRP Devices for Temporary Cardiopulmonary and Circulatory Bypass are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device. (Proposed 21 CFR 870.4360(a)(1); see 21 CFR 801.109 (Prescription devices)).

IX. Dates New Requirements Apply

In accordance with section 515(b) of the FD&C Act, FDA is proposing to require that a PMA be filed with the Agency for NRP Devices for Temporary Ventricular Support within 90 days after issuance of any final order based on this proposal. An applicant whose device was legally in commercial distribution before May 28, 1976, or whose device has been found to be substantially equivalent to such a device, will be permitted to continue marketing such class III devices during FDA's review of the PMA provided that the PMA is timely filed. FDA intends to review any PMA for the device within 180 days of the date of filing. FDA cautions that under section 515(d)(1)(B)(i) of the FD&C Act, the Agency may not enter into an agreement to extend the review period for a PMA beyond 180 days unless the Agency finds that ''the continued availability of the device is necessary for the public health.''

An applicant whose device was legally in commercial distribution before May 28, 1976, or whose device has been found to be substantially equivalent to such a device, who does not intend to market such device for temporary ventricular support, and for which the device technology would allow such device to be used for cardiopulmonary or circulatory bypass, may remove such intended use from the device's labeling by initiating a correction within 90 days after issuance of any final order based on this proposal. Under 21 CFR part 806.10(a)(2) a device manufacturer or importer initiating a correction to remedy a violation of the FD&C Act that may present a risk to health is required to submit a written report of the correction to FDA.

FDA intends that under § 812.2(d), the preamble to any final order based on this proposal will state that, as of the date on which the filing of a PMA is required to be filed, the exemptions from the requirements of the IDE regulations for preamendments class III devices in § 812.2(c)(1) and (c)(2) will cease to apply to any device that is: (1) Not legally on the market on or before that date or (2) legally on the market on or before that date but for which a PMA is not filed by that date, or for which PMA approval has been denied or withdrawn.

If a PMA for a class III device is not filed with FDA within 90 days after the date of issuance of any final order requiring premarket approval for the device, the device would be deemed adulterated under section 501(f) of the FD&C Act. The device may be distributed for investigational use only if the requirements of the IDE regulations are met. The requirements for significant risk devices include submitting an IDE application to FDA

for review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued under § 812.30. FDA, therefore, recommends that IDE applications be submitted to FDA at least 30 days before the end of the 90-day period after the issuance of the final order to avoid interrupting any ongoing investigations.

X. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the FD&C Act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that this device have an approved PMA when used for temporary ventricular support, and (2) the benefits to the public from the use of NRP Devices for Temporary Ventricular Support. These findings are based on the reports and recommendations of the advisory committees (panels) for the classification of these devices along with information submitted in response to the 515(i) Order (74 FR 16214, April 9, 2009), and any additional information that FDA has obtained. Additional information regarding the risks as well as classification associated with this device type is discussed in Section XI of this order and can be found in 44 FR 13409, March 9, 1979; 45 FR 7959, February 5, 1980; 52 FR 17732, May 11, 1987; 58 FR 36290, July 6, 1993; and 69 FR 68831, November 26, 2004.

XI. Device Subject to the Proposal To Require a PMA—Nonroller-Type Temporary Ventricular Support Blood Pump Devices (21 CFR 870.4360(c))

A. Identification

An NRP Device for Temporary Ventricular Support is a prescription device that uses any method resulting in blood propulsion to provide the temporary (i.e. ≤ 6 hours) ventricular assistance required for support of the systemic and/or pulmonary circulations during periods when there is ongoing or anticipated hemodynamic instability due to immediately reversible alterations in ventricular myocardial function resulting from mechanical or physiologic causes.

B. Summary of Data

The use of NRP Devices for Temporary Ventricular Support does not share the long history of use compared to NRP Devices for Temporary Cardiopulmonary or Circulatory Bypass. Temporary NRP devices, when used for cardiopulmonary or circulatory bypass, are integral to the underlying procedure (e.g., open heart surgery, resection of thoracic aneurysm) itself, making it both possible and safer. When used for temporary ventricular support, the NRP devices introduce the risk of both the blood pump and its access technology in procedures where a substantial portion of patient benefit is derived or thought to be derived from the avoidance of circulatory support or bypass, or from the safer performance of the underlying procedure (e.g., percutaneous coronary intervention, off pump coronary artery bypass). Based on FDA's review of available data, use of the device is associated with significant procedural risks. These risks do not appear to be balanced by a demonstrable clinical benefit. Specifically, based on FDA's review of the published literature, it appears that there are no completed studies regarding use of NRP devices that support the effectiveness for temporary ventricular support. Further, the 2011 American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) Guideline for Percutaneous Coronary Intervention assigned a class IIb, Level C recommendation to the use of temporary ventricular support devices for high-risk percutaneous coronary interventions. A Class IIb, level C indication means that the benefit may outweigh the risk and that the treatment or procedure may be considered. This recommendation's usefulness or efficacy is unknown/unclear/uncertain or not well established and is based only on diverging expert opinion, case studies, or standard of care (Ref. 11). When used for temporary ventricular support, FDA concludes that the safety and effectiveness of NRP devices have not been established by adequate scientific evidence. The benefit/risk profile for NRP Devices for Temporary Ventricular Support indications is unknown. Further, safe and effective performance parameters for the class of devices have not been established by data. For these reasons, FDA does not believe sufficient information exists to establish special controls to provide a reasonable assurance of safety and effectiveness for the devices.

FDA presented findings regarding NRP Devices for Temporary Ventricular Support to the Circulatory System Devices Panel (the Panel) on December 6, 2012. The Panel recommended that available scientific evidence is not adequate to support the safety and effectiveness of NRP Devices Temporary Ventricular Support and that these devices fit the criteria necessary to remain in class III because (1) the devices are life-supporting and (2) insufficient information exists to determine that special controls would provide reasonable assurance of its safety and effectiveness for this use. As a result, the Panel concluded that NRP Devices for Temporary Ventricular Support should remain in class III (subject to premarket approval application). The Panel transcript and other meeting materials are available on FDA's Web site (Ref. 11).

C. Risks to Health

The risks to health for NRP Devices for Temporary Ventricular Support include the risks outlined in section V as well as the following additional risks to health:

- *Structural/tissue damage:* Improper design, placement, or use of the percutaneous device or access cannulae can cause structural or tissue damage to the heart or access vessels, including perforation, dissection, tamponade, and/or valve damage.
- *Intracardiac heat generation:* Improper design of the device may cause excessive heat generation within the heart or great vessels, which can cause tissue damage and can affect hemolysis and thromboembolic potential.
- *Modified flow dynamics:* Improper design or placement of the percutaneous device or cannulae can cause new or different patterns or methods of flow, which can affect hemolysis or thromboembolic potential, or can cause limb ischemia due to the need for peripheral cannulation with large bore cannulae.

These additional risks to health are directly related to the NRP technology that, for temporary use, requires percutaneous placement of either a pump containing catheter or separate inflow and outflow cannulae into the heart or great vessels. For effective use, these pump containing catheters or access cannulae must either reside in and/or traverse one or more elements of the circulation (i.e. great vessels, valves, septa). In contrast, temporary NRP devices that are used as part of an extracorporeal cardiopulmonary bypass or circulatory bypass circuit do not present these risks to health since the actual NRP resides outside of the circulation, and the cannulae required for inflow and outflow are placed under direct visualization into the central circulation during an open surgical procedure without being required to traverse one or more cardiac chambers, septa, or valves for effective use.

D. Benefits of NRP Devices for Temporary Ventricular Support

As discussed previously, there is limited scientific evidence regarding the effectiveness of NRP Devices for Temporary Ventricular Support. Because the benefits of NRP Devices for Temporary Ventricular Support are unknown, it is impossible to estimate the direct effect of the devices on patient outcomes. However, NRP Devices for Temporary Ventricular Support have the potential to benefit the public by providing cardiac support, improving hemodynamic stability, reducing myocardial workload and oxygen consumption, and increasing cardiac output. Their use may also allow initiation or completion of complex therapies, recovery of native ventricular function sufficient for weaning of the device, or bridging to more permanent therapies meant to provide long-term hemodynamic support.

XII. PMA Requirements

A PMA for NRP Devices for Temporary Ventricular Support must include the information required by section 515(c)(1) of the FD&C Act and include all data and information on: (1) Any risks known, or that should be reasonably known, to the applicant that have not been identified in this document; (2) the effectiveness of the device that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA must include valid scientific evidence to demonstrate reasonable assurance of the safety and effectiveness of the device for its intended use (see § 860.7(c)(1)). In particular, a PMA for the device should discuss the benefits of the device in light of the risks identified in this document. Valid scientific evidence is ''evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. . . . Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness.'' (See § 860.7(c)(2)).

XIII. Opportunity To Request a Change in Classification

Before requiring the filing of a PMA for a device, FDA is required by section 515(b)(2)(D) of the FD&C Act to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to the classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the FD&C Act.

A request for a change in the classification of NRP Devices for Temporary Ventricular Support is to be in the form of a reclassification petition containing the information required by 21 CFR 860.123, including new information relevant to the classification of the device.

XIV. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices and section 515(b) of the FD&C Act provided for FDA to issue regulations to require approval of an application for premarket approval for preamendments devices or devices found to be substantially equivalent to preamendments devices. Because sections 513(e) and 515(b) as amended require FDA to issue final orders rather than regulations, FDA will continue to codify reclassifications and requirements for approval of an application for premarket approval, resulting from changes issued in final orders, in the Code of Federal Regulations (CFR). Therefore, under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this proposed order, we are proposing to revoke the requirements in 21 CFR 870.4360 related to the classification of nonroller-type cardiopulmonary bypass blood pump devices as class III devices and to codify the reclassification of nonroller-type cardiopulmonary and circulatory bypass blood pump devices into class II.

XV. 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.

XVI. Paperwork Reduction Act of 1995

This proposed order refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231. The collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120. The effect of this order, if finalized, is to shift certain devices from the 510(k) premarket notification process to the PMA process. To account for this change, FDA intends to transfer some of the burden from OMB control number 0910–0120, which is the control number for the 510(k) premarket notification process, to OMB control number 0910–0231, which is the control number for the PMA process. As noted previously, FDA estimates that it will receive three new PMAs as a result of this order, if finalized. Based on FDA's most recent estimates, this will result in 1,038 hours burden increase to OMB control number 0910–0231. FDA also estimates that there will be three fewer 510(k) submissions as a result of this order, if finalized. Based on FDA's most recent estimates, this will result in a 136 hours burden decrease to OMB control number 0910–0120. Therefore, on net, FDA expects a burden hour increase of 901 hours due to this proposed regulatory change.

XVII. Proposed Effective Date

FDA is proposing that any final order based on this proposed order become effective 90 days after date of publication of the final order in the **Federal Register**.

XVIII. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to submit one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

XIX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this reference

section, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

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2. Parolari, A., F. Alamanni, M. Naliato, et al., ''Adult Cardiac Surgery Outcomes: Role of the Pump Type,'' *European Journal of Cardiothoracic Surgery,* vol. 18, pp. 575–582, 2000.
3. Zirbel, G.M., M.E. Letson, J.N. Kauffman, et al., ''Hematologic Derangements of Cardiopulmonary Bypass: A Comparison of Two Perfusion Systems,'' *The Journal of Extra-Corporeal Technology,* vol. 22, pp. 15–19, 1990.
4. Schepens, M.A., F.E. Vermeulen, W.J. Morshuis, et al., ''Impact of Left Heart Bypass on the Results of Thoracoabdominal Aortic Aneurysm Repair,'' *The Annals of Thoracic Surgery,* vol. 67, pp. 1963–1967; discussion pp. 1979–1980, 1999.
5. Szwerc, M.F., D.H. Benckart, J.C. Lin, et al., ''Recent Clinical Experience With Left Heart Bypass Using a Centrifugal Pump for Repair of Traumatic Aortic Transection,'' *Annals of Surgery,* vol. 230, pp. 484–490; discussion pp. 490–492, 1999.
6. Ataka, K., M. Okada, C. Yamashita, et al., ''Beneficial Circulatory Support by Left Heart Bypass With a Centrifugal (BioMedicus) Pump for Aneurysms of the Descending Thoracic Aorta,'' *Artificial Organs,* vol. 17, pp. 300–306, 1993.
7. Galla, J.D., M.A. Ergin, A.M. Sadeghi, et al., ''A New Technique Using Somatosensory Evoked Potential Guidance During Descending and Thoracoabdominal Aortic Repairs,'' *Journal of Cardiac Surgery,* vol. 9, pp. 662–672, 1994.
8. Hess, P.J., H.R. Howe, Jr., and F. Robicsek, ''Traumatic Tears of the Thoracic Aorta: Improved Results Using the Bio-Medicus Pump,'' *The Annals of Thoracic Surgery,* vol. 48, pp. 6–9, 1989.
9. Cunningham, I.N., J.C. Laschinger, and F.C. Spencer, ''Monitoring of Somatosensory Evoked Potentials During Surgical Procedures on the Thoracoabdominal Aorta: Clinical Observations and Results,'' *Journal of Thoracic and Cardiovascular Surgery,* vol. 94, pp. 275–285, 1987.
10. The 2012 Panel transcript and other meeting materials are available on FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/ucm300073.htm.*
11. Levine, G.N., E.R. Bates, J.C. Blankenship, et al., ''2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions,'' *Journal of the American College of Cardiology,* vol. 58, pp. e44–e122, 2011.

List of Subjects in 21 CFR Part 870

Medical devices, Cardiovascular devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 870 be amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for 21 CFR part 870 continues to read as follows:

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

■ 2. Revise § 870.4360 to read as follows:

§ 870.4360 Nonroller-type blood pump.

(a) *Cardiopulmonary and circulatory bypass blood pump*—(1) *Identification.* A nonroller-type cardiopulmonary and circulatory bypass blood pump is a prescription device that uses a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:

(i) Full or partial cardiopulmonary bypass (i.e. circuit includes an oxygenator) during open surgical procedures on the heart or great vessels, or

(ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

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

(i) Nonclinical performance testing must provide a reasonable assurance of safety and effectiveness with respect to the operating parameters, dynamic blood damage, heat generation, air entrapment, mechanical integrity, and durability/reliability to perform as intended over the intended duration of use;

(ii) The device must be demonstrated to be biocompatible;

(iii) Sterility and shelf-life testing must demonstrate the sterility of patient-contacting components and the shelf-life of these components; and

(iv) Labeling must include information regarding the duration of use, and a detailed summary of the device- and procedure-related complications pertinent to use of the device.

(b) *Temporary ventricular support blood pump.*—(1) *Identification.* A nonroller-type temporary ventricular support blood pump is a prescription device that uses any method resulting in blood propulsion to provide the temporary ventricular assistance required for support of the systemic and/or pulmonary circulations during periods when there is ongoing or anticipated hemodynamic instability due to immediately reversible alterations in ventricular myocardial function resulting from mechanical or physiologic causes. Duration of use would be less than 6 hours.

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

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with FDA on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER IN THE **Federal Register**], for any temporary ventricular support blood pump that was in commercial distribution before May 28, 1976, or that has, on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER IN THE **Federal Register**], been found to be substantially equivalent to any temporary ventricular support blood pump that was in commercial distribution before May 28, 1976. Any other temporary ventricular support blood pump shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: January 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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