heading of this document. Any objections received in response to the regulation 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.* We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

IX. 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.*

1. FDA Memorandum from H. Lee, Chemistry Review Group, Division of Petition Review, to E. Anderson, Regulatory Group II, Division of Petition Review, January 5, 2015.
2. FDA Memorandum from H. Lee, Chemistry Review Group, Division of Petition Review, to E. Anderson, Regulatory Group II, Division of Petition Review, March 13, 2015.
3. FDA Memorandum from S. Park, Toxicology Team, Division of Petition Review, to E. Anderson, Regulatory Group II, Division of Petition Review, March 18, 2015.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Section 73.350 is amended by revising paragraph (c)(1)(ii) and by adding paragraph (c)(1)(iii) to read as follows:

§ 73.350 Mica-based pearlescent pigments.

* * * * *

(c) * * *

(1) * * *

(ii) In amounts up to 0.07 percent, by weight, in the following:

(A) Distilled spirits containing not less than 18 percent and not more than 23 percent alcohol by volume but not including distilled spirits mixtures containing more than 5 percent wine on a proof gallon basis.

(B) Cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, and cocktails.

(C) Non-alcoholic cocktail mixes and mixers, such as margarita mix, Bloody Mary mix, and daiquiri mix, but excluding eggnog, tonic water, and beverages that are typically consumed without added alcohol (*e.g.,* fruit juices, fruit juice drinks, and soft drinks).

(iii) In egg decorating kits used for coloring the shells of eggs in amounts consistent with good manufacturing practice.

* * * * *

Dated: June 2, 2015.

Susan Bernard,

Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

[FR Doc. 2015–13834 Filed 6–5–15; 8:45 am]

BILLING CODE 4164–01–P

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: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify nonroller-type cardiopulmonary bypass blood pump (NRP) devices for cardiopulmonary and circulatory bypass, a preamendments class III device, into class II (special controls), and to require the filing of a premarket approval application (PMA) for NRP devices for temporary ventricular support. FDA is also revising the title and identification of the regulation for NRP devices in this order.

DATES: This order is effective June 8, 2015.

FOR FURTHER INFORMATION CONTACT: Fernando Aguel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1234, Silver Spring, MD 20993, 301–796–6326, *fernando.aguel@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), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, 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) (the Panel); (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 (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 or until the device is subsequently reclassified into class I or class II. Section 515(b)(1) of the FD&C Act directs FDA to issue an order requiring premarket approval for a preamendments class III device.

Although, under the FD&C Act, the manufacturer of class III preamendments device may respond to the call for PMAs by filing a PMA or a notice of completion of a product development protocol (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 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 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 reclassifying NRP devices for cardiopulmonary and circulatory bypass from class III to class II (special controls) and renaming these devices from ''Nonroller-type cardiopulmonary bypass blood pump'' to ''Nonroller-type blood pump.''

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) of the FD&C Act must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, *e.g., General Medical Co.* v. *FDA,* 770 F.2d at 214 (D.C. Cir. 1985); *Contact Lens Manufacturers Association* v. *FDA,* 766 F.2d at 592 (D.C. Cir. 1985), 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 non-clinical 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 held a meeting of a device classification panel described in section 513(b) of the FD&C Act with respect to NRP devices on December 6, 2012 (Ref. 1). The Panel unanimously recommended that NRP devices for cardiopulmonary and circulatory bypass be reclassified from class III to class II with special controls because the application of general and special controls are sufficient to provide reasonable assurance of safety and effectiveness for NRP devices when intended for these uses. The Panel believed that the special controls identified by FDA were appropriate to mitigate the relevant risks to health for these uses. FDA published a proposed order in the **Federal Register** on January 7, 2014 (79 FR 765). FDA received and has considered two comments on the proposed order as discussed in section II of this document (Ref. 2).

B. Requirement for Premarket Approval Application

FDA is requiring PMAs for NRP 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.

FDA held a meeting of a device classification panel described in section 513(b) of the FD&C Act with respect to NRP devices on December 6, 2012 (Ref. 1). The majority of the Panel recommended that NRP devices for temporary ventricular support remain in class III (subject to premarket approval application) because there was insufficient information to establish special controls, and that the application of general controls is insufficient to provide a reasonable assurance of safety and effectiveness for NRP devices, which are life-supporting devices (Ref. 2).

FDA published a proposed order in the **Federal Register** of January 7, 2014, that satisfied the requirements of section 515(b)(2) of the FD&C Act, which 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 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. FDA received and has considered two comments on the proposed order as discussed in section II of this document.

A preamendments class III device may be commercially distributed without a PMA until 90 days after FDA issues a final order 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. Since NRP devices (the preamendments class III devices that are the subject of this final order) were classified in 1980, the 30-month period has expired (45 FR 7959, February 5, 1980). Thus, for these devices, the later of these two time periods is the 90-day period. Therefore, section 501(f)(2)(B) of the FD&C Act (21 U.S.C. 351(f)(2)(B)) requires that a PMA for such devices be filed within 90 days of the date of issuance of this final order. If a PMA is not filed for such devices within 90 days after the issuance of this final order, the device will be deemed adulterated under section 501(f) of the FD&C Act.

Also, a preamendments device subject to a call for PMAs 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 for NRP devices for temporary ventricular support. 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 may be subject to injunction under section 302 of the FD&C Act (21 U.S.C. 332), and the individuals responsible for such shipment may be subject to prosecution under section 303 of the FD&C Act (21 U.S.C. 333). FDA requests that manufacturers take action to prevent the further use of devices for which no PMA has been filed.

II. Public Comments in Response to the Proposed Order

In response to the January 7, 2014, proposed order to reclassify NRP devices for cardiopulmonary and circulatory bypass into class II and to require the filing of a PMA for NRP devices for temporary ventricular support, FDA received two comments. One comment disagreed with FDA's proposal to reclassify NRP devices for cardiopulmonary and circulatory bypass as a class II medical device. The comment stated general concerns that reclassification would result in the loss of important safeguards that are provided by authorities under the PMA regime, including proof of safety and efficacy based on short-term clinical trials, reporting of postmarket long-term clinical data as a condition of approval, inspection of manufacturing facilities prior to approval of a device, and the ability to rescind the approval of devices if the device is later found to be unsafe. FDA disagrees with this comment. Currently, NRP devices are typically regulated through the 510(k) pathway; therefore, reclassification of NRP devices for cardiopulmonary and circulatory bypass to class II will not result in the loss of current safeguards, as the regulatory pathway for these devices will remain the same. FDA places a device in the lowest classification that would provide reasonable assurance of the safety and effectiveness of the device. Under section 513(a)(1)(B) of the FD&C Act, a class II device is defined as a device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance. The Panel recommended that NRP devices for cardiopulmonary and circulatory bypass be classified as class II because they believed that there is significant knowledge and data regarding the safety and effectiveness of NRP devices for cardiopulmonary and circulatory bypass, based on the device's long history of use in cardiopulmonary and circulatory bypass procedures (Ref. 2). The Panel believed that the application of general and special controls is sufficient to provide reasonable assurance of safety and effectiveness for NRP devices for cardiopulmonary and circulatory bypass (Ref. 2). FDA agrees with the Panel's recommendation and believes that because special controls are able to provide a reasonable assurance of safety and effectiveness, the requirement of a PMA for these devices is not necessary. By contrast, the majority of the Panel believed there remains insufficient valid scientific evidence to determine that general and special controls would provide a reasonable assurance of safety and effectiveness of NRP devices for temporary ventricular support. FDA agrees with the Panel's recommendation and as a result, NRP devices for temporary ventricular support will remain in class III and require premarket approval.

Another comment supported FDA's proposal to call for PMAs for NRP devices for temporary ventricular support, but disagreed with FDA's intent to reclassify NRP devices for cardiopulmonary and circulatory bypass, stating that ''down-classification . . . would create an enormous and dangerous loophole'' by which devices cleared by the 510(k) process for a ''particular indication'' could be used ''off-label for treatments that require a PMA.'' FDA notes in response to this comment that generally, FDA regulates the use of a device as indicated by the party offering the device for interstate commerce. The indications for NRP devices for cardiopulmonary and circulatory bypass will be limited by the codified identification in § 870.4360(a)(1) (21 CFR 870.4360(a)(1)).

The commenter also expressed concern that special controls were insufficient to mitigate the risk of stroke, peripheral emboli, or death associated with NRP devices for cardiopulmonary and circulatory bypass. FDA disagrees with the commenter. Under section 513(a)(1)(C) of the FD&C Act, a class III device is defined as a device which (1) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device; (2) cannot be classified as a class II device because insufficient information exists to determine that the special controls would provide reasonable assurance of its safety and effectiveness; and (3) is purported or represented to be for a use in supporting or sustaining human life or for a use that is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. FDA believes that sufficient information exists for NRP devices used for

cardiopulmonary and circulatory bypass to establish special controls that, together with general controls, can provide a reasonable assurance of safety and effectiveness and mitigate the risks to health identified in the proposed order (79 FR 765 at 769, January 7, 2014). Stroke, peripheral emboli, and death are potential clinical consequences of the identified risks to health and are therefore addressed by mitigating the risks to health through the general and special controls. Specifically, in the proposed order (79 FR 765 at 769), FDA determined that embolism was a risk to health associated with use of NRP devices for temporary cardiopulmonary and circulatory bypass. We explicitly noted that 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. However, this risk to health is mitigated through non-clinical performance testing and labeling (special controls (a)(2)(i) and (iv) in the codified section of this document). Non-clinical performance testing evaluates the design of the device to ensure that the device does not generate gaseous, particular, or thrombotic emboli, which could cause stroke, peripheral emboli, or death. Further, the labeling will provide information regarding the duration of use to minimize the risk of embolism. The Panel concluded that these special controls were sufficient to mitigate the identified risks to health and provide reasonable assurance of safety and effectiveness for NRP devices for cardiopulmonary and circulatory bypass (Ref. 2). FDA agrees with the Panel's recommendation.

The commenter also provided a summary of adverse event reports for this device type from FDA's Manufacturer and User Facility Device Experience (MAUDE) database to support the perspective that reclassification is inappropriate for NRP devices for cardiopulmonary and circulatory bypass. FDA is aware of this data, fully considered this information prior to the proposed reclassification, and presented the adverse event information to the 2012 Panel that ultimately recommended that FDA reclassify NRP devices for cardiopulmonary and circulatory bypass from class III to class II (special controls). FDA agrees with this recommendation because special controls established by this final order can provide a reasonable assurance of safety and effectiveness.

The commenter further expressed concern that ''down-classification of these devices means that companies manufacturing new models with unique characteristics in the future would not be required to prove that their products are safe or effective. The companies would only need to prove that their products are substantially equivalent to other NRPs for cardiopulmonary and circulatory bypass already on the market, and would not require scientific evidence to ensure equivalent safety or efficacy.'' FDA disagrees with this comment. FDA believes that the special controls will provide a reasonable assurance of safety and effectiveness for NRP devices indicated for cardiopulmonary and circulatory bypass. Conformance with the identified special controls will provide a reasonable assurance of safety and effectiveness for the available predicate NRPs when indicated for cardiopulmonary and circulatory bypass. Future devices claiming substantial equivalence to an available predicate(s) must demonstrate that they are substantially equivalent, as defined under section 513(i) of the FD&C Act, to the predicate device and comply with all applicable FDA regulations. Future devices will also need to comply with the special controls in order to be classified into class II.

III. The Final Order

Under sections 513(e) and 515(b) of the FD&C Act, FDA is adopting its findings as published in the proposed order (79 FR 765). FDA is issuing this final order to reclassify NRP devices for cardiopulmonary and circulatory bypass from class III to class II and establish special controls. In addition, FDA is issuing this final order to require the filing of a PMA for NRP devices for temporary ventricular support.

In accordance with the proposed order, this final order will revise the title and identification of the regulation for NRP devices in 21 CFR part 870 to reflect the different types of NRP devices, their respective intended uses, and their respective classifications.

A. NRP Device for Temporary Ventricular Support

Under the final order, a PMA is required to be filed on or before 90 days after the date of publication of the final order in the **Federal Register** for any class III preamendments NRP devices for temporary ventricular support that were in commercial distribution before May 28, 1976, or that have been found by FDA to be substantially equivalent to such a device on or before 90 days after the date of publication of the final order in the **Federal Register**. An approved PMA is required to be in effect for these devices on or before 180 days after FDA files the application. Any other class III preamendments device subject to this order that was not in commercial distribution before May 28, 1976, is required to have an approved PMA in effect before it may be marketed.

If a PMA or a notice of completion of a PDP for any of the class III preamendments NRP devices intended for temporary ventricular support is not filed on or before the 90th day after the effective date of this final order, that device will be deemed adulterated under section 501(f)(1)(A) of the FD&C Act, and commercial distribution of the device must cease. The device may, however, be distributed for investigational use, if the requirements of the IDE regulations (part 812) are met.

B. NRP Device for Cardiopulmonary and Circulatory Bypass

Following the effective date of this final order, firms submitting a 510(k) premarket notification for a NRP device for cardiopulmonary and circulatory bypass must comply with the particular mitigation measures set forth in the codified special controls.

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 devices. FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of NRP devices for cardiopulmonary and circulatory bypass, and therefore, this device type is not exempt from premarket notification requirements.

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, and who does not intend to market such device for uses other than cardiopulmonary and circulatory bypass, must remove uses other than cardiopulmonary and circulatory bypass from the device's labeling and comply with the special controls to remain legally on the market.

IV. Environmental Impact

The Agency has determined under 21 CFR 25.30 (h) and 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.

V. Paperwork Reduction Act of 1995

This final order refers to previously approved collections of information found in FDA regulations. 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. 3501–3520). The collections of information in part 812 have been approved under OMB control number 0910–0078; 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 part 814, subpart B, have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

VI. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) 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 preamendment devices or devices found to be substantially equivalent to preamendments devices. Sections 513(e) and 515(b) as amended require FDA to issue final orders rather than regulations, and FDASIA provided for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations. Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this final order, we are revoking the requirements in § 870.4360 related to the classification of NRP devices for cardiopulmonary and circulatory bypass as class III devices and codifying the reclassification of these devices into class II.

VII. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 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 addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting, December 5–6, 2012, available at *http://www.fda.gov/AdvisoryCommittees/Calendar/ucm327178.htm.*
2. Transcript of the December 6, 2012, meeting of the Circulatory System Devices Panel, available at *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM335464.pdf.*

List of Subjects in 21 CFR Part 870

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 870 is 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) *Nonroller-type 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) Non-clinical performance testing must perform as intended over the intended duration of use and demonstrate the following: Operating parameters, dynamic blood damage, heat generation, air entrapment, mechanical integrity, and durability/reliability;

(ii) The patient-contacting components of 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) *Nonroller-type 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 September 8, 2015, for any nonroller-type temporary ventricular support blood pump that was in commercial distribution before May 28, 1976, or that has, on or before September 8, 2015, been found to be substantially equivalent to any nonroller-type temporary ventricular support blood pump that was in commercial distribution before May 28, 1976. Any other nonroller-type temporary ventricular support blood pump shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: June 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13889 Filed 6–5–15; 8:45 am]

BILLING CODE 4164–01–P