requirements. Persons who intend to market this type of device must submit to FDA a premarket notification (510(k)), prior to marketing the device, which contains information about the assayed quality control material for clinical microbiology assays they intend to market.

II. Analysis of Environmental Impact

We have 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.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other 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 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR parts 801 and 809, regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

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

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

■ 2. Add § 866.3920 to subpart D to read as follows:

§ 866.3920 Assayed quality control material for clinical microbiology assays.

(a) *Identification.* An assayed quality control material for clinical microbiology assays is a device indicated for use in a test system to estimate test precision or to detect systematic analytical deviations that may arise from reagent or analytical instrument variation. This type of device consists of single or multiple microbiological analytes intended for use with either qualitative or quantitative assays.

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

(1) Premarket notification submissions must include detailed device description documentation and information concerning the composition of the quality control material, including, as appropriate:

(i) Analyte concentration;

(ii) Expected values;

(iii) Analyte source;

(iv) Base matrix;

(v) Added components;

(vi) Safety and handling information; and

(vii) Detailed instructions for use.

(2) Premarket notification submissions must include detailed documentation, including line data as well as detailed study protocols and a statistical analysis plan used to establish performance, including:

(i) Description of the process for value assignment and validation.

(ii) Description of the protocol(s) used to establish stability.

(iii) Line data establishing precision/reproducibility.

(iv) Where applicable, assessment of matrix effects and any significant differences between the quality control material and typical patient samples in terms of conditions known to cause analytical error or affect assay performance.

(v) Where applicable, identify or define traceability or relationship to a domestic or international standard reference material and/or method.

(vi) Where applicable, detailed documentation related to studies for surrogate controls.

(3) Premarket notification submissions must include an adequate mitigation (*e.g.,* real-time stability program) to the risk of false results due to potential modifications to the assays specified in the device's 21 CFR 809.10 compliant labeling.

(4) Your 21 CFR 809.10 compliant labeling must include the following:

(i) The intended use of your 21 CFR 809.10(a)(2) and (b)(2) compliant labeling must include the following:

(A) Assayed control material analyte(s);

(B) Whether the material is intended for quantitative or qualitative assays;

(C) Stating if the material is a surrogate control; and

(D) The system(s), instrument(s), or test(s) for which the quality control material is intended.

(ii) The intended use in your 21 CFR 809.10(a)(2) and (b)(2) compliant labeling must include the following statement: ''This product is not intended to replace manufacturer controls provided with the device.''

(iii) A limiting statement that reads ''Quality control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.''

Dated: July 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–15858 Filed 7–26–17; 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–2017–N–1916]

Medical Devices; Cardiovascular Devices; Classification of the Balloon Aortic Valvuloplasty Catheter

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the balloon aortic valvuloplasty catheter into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the balloon aortic valvuloplasty catheter's classification. The Agency is classifying the device into class II (special controls) to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective July 27, 2017. The classification was applicable on June 11, 2012.

FOR FURTHER INFORMATION CONTACT: Nicole Ibrahim, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1232, Silver Spring, MD, 20993–0002, 301–796–5171, *nicole.ibrahim@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA

rulemaking process. These devices remain in class III and require premarket approval unless and until the device is classified or 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) of the regulations.

Section 513(f)(2) of the FD&C Act, also known as De Novo classification, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device. In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on December 3, 2008, classifying the NuCLEUS–X Percutaneous Transluminal Valvuloplasty Catheter into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II.

On December 23, 2008, NuMED, Inc. submitted a request for classification of the NuCLEUS–X Percutaneous Transluminal Valvuloplasty Catheter under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on June 11, 2012, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 870.1255.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a balloon aortic valvuloplasty catheter will need to comply with the special controls named in this final order. A De Novo classification decreases regulatory burdens. When FDA classifies a device type as class I or II via the De Novo pathway, other manufacturers do not have to submit a De Novo request or premarket approval application to market the same type of device, unless the device has a new intended use or technological characteristics that raise different questions of safety or effectiveness. Instead, manufacturers can use the less burdensome pathway of 510(k), when necessary, to market their device, and the device that was the subject of the original De Novo classification can serve as a predicate device for additional 510(k)s from other manufacturers.

The device is assigned the generic name balloon aortic valvuloplasty catheter, and it is identified as a catheter with a balloon at the distal end of the shaft that is intended to treat stenosis in the aortic valve when the balloon is expanded.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1:

TABLE 1—BALLOON AORTIC VALVULOPLASTY CATHETER RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction	Biocompatibility testing. Labeling.
Infection	Sterility. Shelf life testing. Labeling.
User error	Labeling.
Valve leaflet perforation	Non-clinical performance evaluation. In Vivo evaluation. Labeling.
Perforation of vascular or cardiac tissue	Non-clinical performance evaluation. In Vivo evaluation. Labeling.
Procedural complications, including bleeding, cardiac tamponade, calcium embolic events, valvular regurgitation, and death.	Non-clinical performance evaluation. In Vivo evaluation. Labeling.
Balloon burst	Non-clinical performance evaluation. In Vivo evaluation. Labeling.

TABLE 1—BALLOON AORTIC VALVULOPLASTY CATHETER RISKS AND MITIGATION MEASURES—Continued

Identified risks	Mitigation measures
Inability for balloon deflation	Non-clinical performance evaluation. In Vivo evaluation.
Increased balloon inflation and deflation times	Non-clinical performance evaluation. In Vivo evaluation. Labeling.
Inability to steer towards valve of interest	Non-clinical performance evaluation. In Vivo evaluation.

FDA believes that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness.

Balloon aortic valvuloplasty catheters are not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109, *Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification (510(k)), prior to marketing the device, which contains information about the balloon aortic valvuloplasty catheter they intend to market.

II. Analysis of Environmental Impact

We have 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.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other 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 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

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 part 870 continues to read as follows:

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

■ 2. Add § 870.1255 to subpart B to read as follows:

§ 870.1255 Balloon aortic valvuloplasty catheter.

(a) *Identification.* A balloon aortic valvuloplasty catheter is a catheter with a balloon at the distal end of the shaft, which is intended to treat stenosis in the aortic valve when the balloon is expanded.

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

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

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

(3) Non-clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use, including device delivery, inflation, deflation, and removal.

(4) In vivo evaluation of the device must demonstrate device performance, including the ability of the device to treat aortic stenosis.

(5) Labeling must include a detailed summary of the device-related and procedure-related complications pertinent to the use of the device.

Dated: July 21, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–15786 Filed 7–26–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 147

[Public Notice: 10027]

RIN 1400–AE42

Electronic and Information Technology

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule provides a correction to a hyperlink included in the Section 508 implementing rule for the Department of State (the Department). The hyperlink takes the reader to a form that can be used by an employee or a member of the public to report accessibility issues to the Department, regarding its electronic and information technology.

DATES: This rule is effective on August 28, 2017.

FOR FURTHER INFORMATION CONTACT: Alice Kottmyer, Attorney-Adviser, 202–647–2318, *kottmyeram@state.gov.*

SUPPLEMENTARY INFORMATION: Section 508 requires that when Federal departments and agencies develop, procure, maintain, or use electronic and information technology, they shall ensure that the electronic and information technology is accessible to individuals with disabilities. The Department's implementing regulations, in 22 CFR part 147, were published in 2016. Due to a re-configuration of Web site assets within the Department, the hyperlink included in § 147.7(c) for the DS–4282 (Discrimination Complaint Form), is no longer valid. This rulemaking corrects the link.

The Department is preparing a more comprehensive update to Part 147, which will align its rule with the final rule published by the Access Board (*see* 82 FR 5790); and to parts 142 and 144