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:


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
undertake the classification request if

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>
<thead>
<tr>
<th>Identified risks</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse tissue reaction</td>
<td>Biocompatibility testing.</td>
</tr>
<tr>
<td>Infection</td>
<td>Labeling.</td>
</tr>
<tr>
<td>User error</td>
<td>Sterility.</td>
</tr>
<tr>
<td>Valve leaflet perforation</td>
<td>Shelf life testing.</td>
</tr>
<tr>
<td>Perforation of vascular or cardiac tissue</td>
<td>Labeling.</td>
</tr>
</tbody>
</table>
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(l)(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

§ 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).

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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.

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