quality controls that are recommended or provided. The description must identify those control elements that are incorporated into the recommended testing procedures;

(D) Detailed description and specifications for sample preparation, processing, and storage, if applicable;

(E) Methodology and protocols for detecting fluorescence and visualizing results; and

(F) Detailed specification of the criteria for test results interpretation and reporting.

(ii) Data demonstrating the performance characteristics of the device, which must include:

(A) A comparison study of the results obtained with the conventional manual method (*i.e.,* reference standard), the device, and the reading of the digital image without aid of the software, using the same set of patient samples for each. The study must use a legally marketed assay intended for use with the device. Patient samples must be from the assay-specific intended use population and differential diagnosis population. Samples must also cover the assay measuring range, if applicable;

(B) Device clinical performance established by comparing device results at multiple U.S. sites to the clinical diagnostic standard used in the United States, using patient samples from the assay-specific intended use population and the differential diagnosis population. For all samples, the diagnostic clinical criteria and the demographic information must be collected and provided. Clinical validation must be based on the determination of clinical sensitivity and clinical specificity using the test results (*e.g.,* antibody status based on fluorescence to include pattern and titer, if applicable) compared to the clinical diagnosis of the subject from whom the clinical sample was obtained. The data must be summarized in tabular format comparing the result generated by automated, manual, and digital only interpretation to the disease status;

(C) Device precision/reproducibility data generated from within-run, between-run, between-day, between-lot, between-operator, between-instruments, between-site, and total precision for multiple nonconsecutive days (as applicable) using multiple operators, multiple instruments and at multiple sites. A well-characterized panel of patient samples or pools from the associated assay specific intended use population must be used;

(D) Device linearity data generated from patient samples covering the assay measuring range, if applicable;

(E) Device analytical sensitivity data, including limit of blank, limit of detection, and limit of quantitation, if applicable;

(F) Device assay specific cutoff, if applicable;

(G) Device analytical specificity data, including interference by endogenous and exogenous substances, if applicable;

(H) Device instrument carryover data, if applicable;

(I) Device stability data including real-time stability under various storage times and temperatures, if applicable; and

(J) Information on traceability to a reference material and description of value assignment of calibrators and controls, if applicable.

(iii) Identification of risk mitigation elements used by the device, including description of all additional procedures, methods, and practices, incorporated into the directions for use that mitigate risks associated with testing.

(3) Your 21 CFR 809.10 compliant labeling must include:

(i) A warning statement that reads ''The device is for use by a trained operator in a clinical laboratory setting'';

(ii) A warning statement that reads ''All software-aided results must be confirmed by the trained operator'';

(iii) A warning statement that reads ''This device is only for use with reagents that are indicated for use with the device''; and

(iv) A description of the protocol and performance studies performed in accordance with paragraph (b)(2)(ii) of this section and a summary of the results, if applicable.

Dated: November 7, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–24585 Filed 11–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2017–N–6289]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Prostatic Artery Embolization Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the prostatic artery embolization device into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the prostatic artery embolization device's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective November 14, 2017. The classification was applicable on June 21, 2017.

FOR FURTHER INFORMATION CONTACT: Benjamin Fisher, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G108, Silver Spring, MD 20993–0002, 301–796–0245, *Benjamin.Fisher@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the prostatic artery embolization device as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures

for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)). Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or pre-market approval in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On August 5, 2016, BioSphere Medical, S.A., submitted a request for De Novo classification of the Embosphere® Microspheres. FDA reviewed the request to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify 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 that, in combination with the generals controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on June 21, 2017, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 876.5550. We have named the generic type of device prostatic artery embolization device, and it is identified as an intravascular implant intended to occlude the prostatic arteries to prevent blood flow to the targeted area of the prostate, resulting in a reduction of lower urinary tract symptoms related to benign prostatic hyperplasia. This does not include cyanoacrylates and other embolic agents which act by in situ polymerization or precipitation, or embolization devices used in neurovascular applications (see 21 CFR 882.5950).

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—PROSTATIC ARTERY EMBOLIZATION DEVICE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Infection	Sterilization validation, Shelf-life validation, Non-clinical performance testing, and Labeling.
Non-target ischemia	Clinical data, Non-clinical performance testing, and Labeling.
Urinary retention	Labeling.
Post-prostatic artery embolization syndrome (nausea, vomiting, regional pain, non-infectious fever, minor hematuria, or hematochezia).	Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k).

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. 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 the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in part 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; 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 876

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 876 is amended as follows:

PART 876—GASTROENTEROLOGY–UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

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

■ 2. Add § 876.5550 to subpart F to read as follows:

§ 876.5550 Prostatic artery embolization device.

(a) *Identification.* A prostatic artery embolization device is an intravascular implant intended to occlude the prostatic arteries to prevent blood flow to the targeted area of the prostate, resulting in a reduction of lower urinary tract symptoms related to benign prostatic hyperplasia. This does not include cyanoacrylates and other embolic agents which act by in situ polymerization or precipitation, or embolization devices used in neurovascular applications (see 21 CFR 882.5950).

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

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

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Evaluation of suitability for injection through catheters intended for use in embolization; and

(ii) Evaluation of the size distribution of the device.

(3) Performance data must support the sterility and pyrogenicity of the device.

(4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(5) Clinical data must evaluate post-embolization damage due to non-target embolization under anticipated use conditions.

(6) The labeling must include:

(i) Specific instructions on safe device preparation and use;

(ii) The device shelf life;

(iii) Data regarding urinary retention; and

(iv) Data regarding post-prostatic artery embolization syndrome.

Dated: November 7, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–24586 Filed 11–13–17; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2016–0369; FRL–9970–70–Region 3]

Determination of Attainment by the Attainment Date for the 2008 Ozone National Ambient Air Quality Standard; District of Columbia, Maryland, and Virginia; Washington, DC-MD-VA Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is making a final determination that the Washington, DC–MD–VA marginal ozone nonattainment area (the Washington Area) attained the 2008 ozone national ambient air quality standard (NAAQS) by the July 20, 2016 attainment date. This determination is based on complete, certified, and quality assured ambient air quality monitoring data for the Washington Area for the 2013–2015 monitoring period. The effect of this determination of attainment is that the Washington Area will not be bumped up or reclassified as a moderate nonattainment area. This determination of attainment is not equivalent to a redesignation, and the states in the Washington Area and the District of Columbia must meet the statutory requirements for redesignation in order to be redesignated to attainment. This determination is also not a clean data determination. This action is being taken under the Clean Air Act (CAA).

DATES: This final rule is effective on December 14, 2017.

ADDRESSES: EPA established a docket for this action under Docket ID Number EPA–R03–OAR–2016–0369. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the docket index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section below for additional availability information.

FOR FURTHER INFORMATION CONTACT: Gavin Huang, (215) 814–2042, or by email at *huang.gavin@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On April 25, 2017 (82 FR 19011), EPA published a notice of proposed rulemaking (NPR) for the Washington Area. The Washington Area consists of the Counties of Calvert, Charles, Frederick, Montgomery, and Prince George's in Maryland; the Counties of Arlington, Fairfax, Loudoun, and Prince William and the Cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park in Virginia; and the entirety of the District of Columbia. In the NPR, EPA proposed to determine, in accordance with its statutory obligations under section 181(b)(2)(A) of the CAA and the Provisions for Implementation of the 2008 Ozone National Ambient Air Quality Standards (40 CFR part 51, subpart AA), that the Washington Area attained the 2008 ozone NAAQS by the applicable attainment date of July 20, 2016.

II. EPA's Evaluation

Section 181(b)(2)(A) of the CAA requires that EPA determine whether an area has attained the NAAQS by its attainment date based on complete and certified air quality data from the three full calendar years preceding an area's attainment date. The 2008 ozone NAAQS level is 0.075 parts per million (ppm). *See* 73 FR 16436 (March 27, 2008). Consistent with the requirements contained in 40 CFR part 50, appendix P, EPA reviewed the ozone ambient air quality monitoring data for each monitoring site within the Washington Area for the monitoring period from 2013 through 2015, as recorded in the Air Quality System (AQS) database. Federal, state, and local agencies responsible for ozone air monitoring networks supplied and quality assured the data. EPA determined that all the Washington Area monitoring sites with valid data had design values equal to or less than 0.075 ppm based on the 2013–2015 monitoring period. Therefore, based on 2013–2015 certified air quality