(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on October 30, 2017.

Jeffrey E. Duven,

Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2017–24166 Filed 11–13–17; 8:45 am]

BILLING CODE 4910–13–P

TENNESSEE VALLEY AUTHORITY

18 CFR Part 1301

Privacy Act Regulations; Correction

Correction

In rule document 2017–24300, appearing on pages 51757–51758 in the issue of Wednesday, November 8, 2017, make the following correction:

■ On page 51757 in the second column, remove Amendatory instruction 2.

Dates: This correction is effective on November 8, 2017.

[FR Doc. C1–2017–24300 Filed 11–9–17; 4:15 pm]

BILLING CODE 1301–00–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2017–N–5881]

Medical Devices; Immunology and Microbiology Devices; Classification of the Automated Indirect Immunofluorescence Microscope and Software-Assisted System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the automated indirect immunofluorescence microscope and software-assisted system 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 automated indirect immunofluorescence microscope and software-assisted system'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 April 9, 2015.

FOR FURTHER INFORMATION CONTACT: Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993–0002, 301–796–5866, *steven.tjoe@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the automated indirect immunofluorescence microscope and software-assisted system 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 (the 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 (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. 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. 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 is required to 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 placed 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 premarket approval application (PMA) 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

For this device, FDA issued an order on November 14, 2014, finding the NOVA View® Automated Fluorescence Microscope not substantially equivalent to a predicate not subject to PMA. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On December 11, 2014, Inova Diagnostics, Inc. submitted a request for De Novo classification of the NOVA

View® Automated Fluorescence Microscope. FDA reviewed the request in order 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 general 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 general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 9, 2015, 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 866.4750. We have named the generic type of device automated indirect immunofluorescence microscope and software-assisted system, and it is identified as a device that acquires, analyzes, stores, and displays digital images of indirect immunofluorescent slides. It is intended to be used as an aid in the determination of antibody status in

clinical samples. The device may include a fluorescence microscope with light source, a motorized microscope stage, dedicated instrument controls, a camera, a computer, a sample processor, or other hardware components. The software may include fluorescent signal acquisition and processing software, data storage and transferring mechanisms, or assay specific algorithms to suggest results. A trained operator must confirm results generated with the device.

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—AUTOMATED INDIRECT IMMUNOFLUORESCENCE MICROSCOPE AND SOFTWARE-ASSISTED SYSTEM RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures/21 CFR section
Inaccurate test results that provide false positive or false negative results.	Special controls (1), (2), and (3) (21 CFR 866.4750(b)(1); 21 CFR 866.4750(b)(2); and 21 CFR 866.4750(b)(3)).
Failure to correctly interpret test results can lead to false positive or false negative results.	Special controls (1), (2)(i), (2)(ii)(A), (2)(ii)(B), (2)(iii), and (3) (21 CFR 866.4750(b)(1); 21 CFR 866.4750(b)(2)(i); 21 CFR 866.4750(b)(2)(ii)(A); 21 CFR 866.4750(b)(2)(ii)(B); 21 CFR 866.4750(b)(2)(iii); and 21 CFR 866.4750(b)(3)).

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) of the FD&C Act.

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 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 continues to read as follows:

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

■ 2. Add § 866.4750 to subpart E to read as follows:

§ 866.4750 Automated indirect immunofluorescence microscope and software-assisted system.

(a) *Identification.* An automated indirect immunofluorescence microscope and software-assisted system is a device that acquires, analyzes, stores, and displays digital images of indirect immunofluorescent slides. It is intended to be used as an aid

in the determination of antibody status in clinical samples. The device may include a fluorescence microscope with light source, a motorized microscope stage, dedicated instrument controls, a camera, a computer, a sample processor, or other hardware components. The software may include fluorescent signal acquisition and processing software, data storage and transferring mechanisms, or assay specific algorithms to suggest results. A trained operator must confirm results generated with the device.

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

(1) The labeling for the device must reference legally marketed assays intended for use with the device.

(2) Premarket notification submissions must include the following information:

(i) A detailed description of the device that includes:

(A) A detailed description of instrumentation and equipment, and illustrations or photographs of non-standard equipment or methods, if applicable;

(B) Detailed documentation of the software, including, but not limited to, stand-alone software applications and hardware-based devices that incorporate software, if applicable;

(C) A detailed description of appropriate internal and external

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