(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