this requirement. As explained above, the adjustments required for years subsequent to 2017 are not subject to the requirements of the Administrative Procedure Act. Moreover, the 2017 adjustments are made according to a statutory formula that does not provide for agency discretion. Accordingly, a delay in effectiveness of the 2017 adjustments is not required.

### IV. Regulatory Requirements

*Regulatory Flexibility Act*

Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis.[9]

*Paperwork Reduction Act*

In accordance with the Paperwork Reduction Act of 1995,[10] NASA reviewed this interim final rule. No collections of information pursuant to the Paperwork Reduction Act are contained in the interim final rule.

### List of Subjects in 14 CFR Parts 1264 and 1271

Claims, Lobbying, Penalties.

For the reasons stated in the preamble, the National Aeronautics and Space Administration adopts as final the interim rule amending 14 CFR parts 1264 and 1271 which published on June 26, 2017, at 82 FR 28760, with the following changes:

## PART 1264—IMPLEMENTATION OF THE PROGRAM FRAUD CIVIL PENALTIES ACT OF 1986

■ 1. The authority citation for part 1264 continues to read as follows:

**Authority:** 31 U.S.C. 3809, 51 U.S.C. 20113(a).

### § 1264.102 [Amended]

■ 2. In § 1264.102, paragraphs (a) and (b), remove the number ''$10,781'' and add in its place the number ''$10,957.''

## PART 1271—NEW RESTRICTIONS ON LOBBYING

■ 3. The authority citation for part 1271 continues to read as follows:

**Authority:** Section 319, Pub. L. 101–121 (31 U.S.C. 1352); Pub. L. 97–258 (31 U.S.C. 6301 *et seq.*)

### § 1271.400 [Amended]

■ 4. In § 1271.400:

■ a. In paragraphs (a) and (b) remove the words ''not less than $18,936 and not more than $189,361'' and add in their place the words ''not less than $19,246 and not more than $192,459.''

■ b. In paragraph (e), remove the two occurrences of ''$18,936'' and add in their place ''$19,246'' and remove ''189,361'' and add in its place ''$192,459''.

### Appendix A to Part 1271 [Amended]

■ 5. In appendix A to part 1271, in the paragraph following paragraph (3) and in the last paragraph of the appendix, remove the words ''not less than $18,936 and not more than $189,361'' and add in their place the words ''not less than $19,246 and not more than $192,459''.

**Nanette J. Smith,**

*NASA Federal Register Liaison Officer.*

[FR Doc. 2017–22847 Filed 10–19–17; 8:45 am]

**BILLING CODE P**

[9] 5 U.S.C. 603(a), 604(a).

[10] 44 U.S.C. 3506.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 866

**[Docket No. FDA–2017–N–5371]**

## Medical Devices; Immunology and Microbiology Devices; Classification of the Device To Detect and Identify Microbial Pathogen Nucleic Acids in Cerebrospinal Fluid

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid into class II (special controls). The special controls that will apply to the device type are identified in this order and will be part of the codified language for the device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid'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 October 20, 2017. The classification was applicable on October 8, 2015.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Sconce, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4524, Silver Spring, MD, 20993–0002, 301–796–6679, *kimberly.sconce@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

Upon request, FDA has classified the device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid 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 (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

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 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 April 9, 2015, BioFire Diagnostics, LLC submitted a request for De Novo classification of the FilmArray® Meningitis/Encephalitis (ME) Panel. 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 October 8, 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 866.3970. We have named the generic type of device, device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid, and it is identified as a qualitative in vitro device intended for the detection and identification of microbial-associated nucleic acid sequences from patients suspected of meningitis or encephalitis. A device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid is intended to aid in the diagnosis of meningitis or encephalitis when used in conjunction with clinical signs and symptoms and other clinical and laboratory findings.

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—DEVICE TO DETECT AND IDENTIFY MICROBIAL PATHOGEN NUCLEIC ACIDS IN CEREBROSPINAL FLUID RISKS AND MITIGATION MEASURES

| Identified risks | Mitigation measures |
|---|---|
| Incorrect identification or lack of identification of a pathogenic microorganism by the device can lead to improper patient management. | Special Controls (1), (2), (3), (4), and (5). |
| Failure to correctly interpret test results | Special Controls (6), (7), (8), and (9). |
| Failure to correctly operate the instrument | Special Control (10). |

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, the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073, 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 § 866.3970 to subpart D to read as follows:

### § 866.3970 Device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid.

(a) *Identification.* A device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid is a qualitative in vitro device intended for the detection and identification of microbial-associated nucleic acid

sequences from patients suspected of meningitis or encephalitis. A device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid is intended to aid in the diagnosis of meningitis or encephalitis when used in conjunction with clinical signs and symptoms and other clinical and laboratory findings.

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

(1) Premarket notification submissions must include detailed device description documentation, including the device components, ancillary reagents required but not provided, and a detailed explanation of the methodology, including primer/probe sequence, design, and rationale for sequence selection.

(2) Premarket notification submissions must include detailed documentation from the following analytical studies: Analytical sensitivity (limit of detection), inclusivity, reproducibility, interference, cross reactivity, and specimen stability.

(3) Premarket notification submissions must include detailed documentation from a clinical study. The study, performed on a study population consistent with the intended use population, must compare the device performance to results obtained from well-accepted comparator methods.

(4) Premarket notification submissions must include detailed documentation for device software, including, but not limited to, software applications and hardware-based devices that incorporate software.

(5) The Intended Use statement in the device labeling must include a statement that the device is intended to be used in conjunction with standard of care culture.

(6) A detailed explanation of the interpretation of results and acceptance criteria must be included in the device's 21 CFR 809.10(b)(9) compliant labeling.

(7) The device labeling must include a limitation stating that the negative results do not preclude the possibility of central nervous system infection.

(8) The device labeling must include a limitation stating that device results are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions.

(9) The device labeling must include a limitation stating that positive results do not mean that the organism detected is infectious or is the causative agent for clinical symptoms.

(10) As part of the risk management activities performed as part of your 21 CFR 820.30 design controls, you must document an appropriate end user device training program that will be offered as part of your efforts to mitigate the risk of failure to correctly operate the instrument.

Dated: October 13, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–22769 Filed 10–19–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF DEFENSE

### Department of the Navy

### 32 CFR Part 706

### Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

**AGENCY:** Department of the Navy, DoD.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Navy (DoN) is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG) (Admiralty and Maritime Law) has determined that certain vessels of the VIRGINIA SSN Class are vessels of the Navy which, due to their special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with their special function as a naval ships. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

**DATES:** This rule is effective October 20, 2017 and is applicable beginning September 30, 2017.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Commander Kyle Fralick, (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave. SE., Suite 3000, Washington Navy Yard, DC 20374–5066, telephone 202–685–5040.

**SUPPLEMENTARY INFORMATION:** Pursuant to the authority granted in 33 U.S.C. 1605, the DoN amends 32 CFR part 706.

This amendment provides notice that the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that certain vessels of the SSN Class are vessels of the Navy which, due to their special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with their special function as a naval ship: Rule 23(a) and Annex I, paragraph 2(a)(i), pertaining to the vertical placement of the masthead, light and Annex I, paragraph 2(f)(i), pertaining to the masthead light being above and clear of all other lights and obstructions; Rule 30 (a), Rule 21(e), and Annex I, paragraph 2(k), pertaining to the vertical separation of the anchor lights, vertical placement of the forward anchor light above the hull, and the arc of visibility of all around lights; Rule 23 (a) and Annex I, paragraph 3(b), pertaining to the location of the sidelights; and Rule 21(c), pertaining to the location and arc of visibility of the sternlight. The DAJAG (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on these vessels in a manner differently from that prescribed herein will adversely affect these vessels' ability to perform their military functions.

**List of Subjects in 32 CFR Part 706**

Marine safety, Navigation (water), Vessels.

For the reasons set forth in the preamble, the DoN amends part 706 of title 32 of the Code of Federal Regulations as follows:

## PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

■ 1. The authority citation for part 706 continues to read as follows:

**Authority:** 33 U.S.C. 1605.

■ 2. Section 706.2 is amended by:

■ a. In Table One, adding, in alpha numerical order, by vessel number, an entry for USS INDIANA (SSN 789);

■ b. In Table Three, adding, in alpha numerical order, by vessel number, an entry for USS INDIANA (SSN 789); and

■ c. In Table Four:

■ i. In paragraph 25, adding, in alpha numerical order, by vessel number, an entry for USS INDIANA (SSN 789); and

■ ii. In paragraph 26, adding, in alpha numerical order, by vessel number, an entry for USS INDIANA (SSN 789).

The additions read as follows:

**§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.**

* * * * *