

available to receive and culture specimens.

(iii) Where the device results interpretation involves combining the outputs of several targets to get the final results, such as a device that both detects Influenza A and differentiates all known Influenza A subtypes that are currently circulating, the device's labeling must include a clear interpretation instruction for all valid and invalid output combinations, and recommendations for any required followup actions or retesting in the case of an unusual or unexpected device result.

(iv) A limiting statement that if a specimen yields a positive result for Influenza A, but produces negative test results for all specific influenza A subtypes intended to be differentiated (i.e., H1–2009 and H3), this result requires notification of appropriate local, State, or Federal public health authorities to determine necessary measures for verification and to further determine whether the specimen represents a novel strain of Influenza A.

(7) If one of the actions listed at section 564(b)(1)(A) through (D) of the Federal Food, Drug, and Cosmetic Act occurs with respect to an influenza viral strain, or if the Secretary of Health and Human Services determines, under section 319(a) of the Public Health Service Act, that a disease or disorder presents a public health emergency, or that a public health emergency otherwise exists, with respect to an influenza viral strain:

(i) Within 30 days from the date that FDA notifies manufacturers that characterized viral samples are available for test evaluation, the manufacturer must have testing performed on the device with those influenza viral samples in accordance with a standardized protocol considered and determined by FDA to be acceptable and appropriate.

(ii) Within 60 days from the date that FDA notifies manufacturers that characterized influenza viral samples are available for test evaluation and continuing until 3 years from that date, the results of the influenza emergency analytical reactivity testing, including the detailed information for the virus tested as described in the certificate of authentication, must be included as part of the device's labeling in a tabular format, either by:

(A) Placing the results directly in the device's labeling required under § 809.10(b) of this chapter that accompanies the device in a separate section of the labeling where analytical reactivity testing data can be found, but

separate from the annual analytical reactivity testing results; or

(B) In a section of the device's label or in other labeling that accompanies the device, prominently providing a hyperlink to the manufacturer's public website where the analytical reactivity testing data can be found. The manufacturer's website, as well as the primary part of the manufacturer's website that discusses the device, must provide a prominently placed hyperlink to the website containing this information and must allow unrestricted viewing access.

Dated: August 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–18266 Filed 8–15–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2024–N–3358]

Medical Devices; Immunology and Microbiology Devices; Classification of the Device To Detect and Identify Selected Microbial Agents That Cause Acute Febrile Illness

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the device to detect and identify selected microbial agents that cause acute febrile illness 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 device to detect and identify selected microbial agents that cause acute febrile illness'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.

DATES: This order is effective August 16, 2024. The classification was applicable on November 20, 2020.

FOR FURTHER INFORMATION CONTACT:

Bryan Grabias, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3260, Silver Spring,

MD 20993–0002, 240–402–9563, Bryan.Grabias@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the device to detect and identify selected microbial agents that cause acute febrile illness 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 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 (see 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 device 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 (see also 21 CFR part 860, subpart D). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. 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.

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 section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially

equivalent device (see section 513(i) of the FD&C Act, defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On June 26, 2020, FDA received BioFire Defense, LLC’s request for De Novo classification of the FilmArray Global Fever 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 the general

controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on November 20, 2020, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 866.3966.¹ We have named the generic type of device as a device to detect and identify selected microbial agents that cause acute febrile illness, and it is identified as an in vitro device intended for the detection and identification of microbial agents in human clinical specimens from patients with signs and symptoms of acute febrile illness who are at risk for exposure or who may have been exposed to these agents. It is intended to aid in the diagnosis of acute febrile illness in conjunction with other clinical, epidemiologic, and laboratory data, including patient travel, pathogen endemicity, or other risk factors.

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 SELECTED MICROBIAL AGENTS THAT CAUSE ACUTE FEBRILE ILLNESS RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Risk of an inaccurate test result (false positive or false negative result) leading to improper patient management.	Certain labeling information, including certain limiting statements and performance information; Certain design verification and validation, including certain analytical studies and clinical studies; and Use of certain specimen collection devices.
Misinterpretation of test results leading to misdiagnosis and associated risk of false test results.	Certain labeling information, including certain limiting statements and performance information; and Certain design verification and validation, including certain analytical studies and clinical studies.
Failure to correctly operate the device leading to inaccurate test results	Certain labeling information, including certain limiting statements and performance information; Certain design verification and validation, including certain analytical studies and clinical studies; and Use of certain specimen collection devices.

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 and guidance. 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. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the

¹ FDA notes that the “ACTION” caption for this final order is styled as “Final amendment; final order,” rather than “Final order.” Beginning in December 2019, this editorial change was made to

indicate that the document “amends” the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register’s (OFR) interpretations of the Federal Register Act (44

U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

collections of information in 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; the collections of information in 21 CFR part 820, regarding quality system regulation, 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, 360l, 371.

■ 2. Add § 866.3966 to read as follows:

§ 866.3966 Device to detect and identify selected microbial agents that cause acute febrile illness.

(a) *Identification.* A device to detect and identify selected microbial agents that cause acute febrile illness is identified as an in vitro device intended for the detection and identification of microbial agents in human clinical specimens from patients with signs and symptoms of acute febrile illness who are at risk for exposure or who may have been exposed to these agents. It is intended to aid in the diagnosis of acute febrile illness in conjunction with other clinical, epidemiologic, and laboratory data, including patient travel, pathogen endemicity, or other risk factors.

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

(1) Any sample collection device used must be FDA-cleared, -approved, or -classified as 510(k) exempt (standalone or as part of a test system) for the collection of specimen types claimed by this device; alternatively, the sample collection device must be cleared in a premarket submission as a part of this device.

(2) The labeling required under § 809.10(b) of this chapter must include:

(i) An intended use that includes a detailed description of targets the device detects and measures, the results provided to the user, the clinical indications appropriate for test use, and the specific population(s) for which the device is intended.

(ii) Limiting statements indicating:

(A) Not all pathogens that cause febrile illness are detected by this test and negative results do not rule out the presence of other infections;

(B) Evaluation of more common causes of acute febrile illness should be considered prior to evaluation with this test;

(C) Test results are to be interpreted in conjunction with other clinical, epidemiologic, and laboratory data available to the clinician; and

(D) When using this test, consider patient travel history and exposure risk, as some pathogens are more common in certain geographical locations.

(iii) A detailed device description, including reagents, instruments, ancillary materials, all control elements, and a detailed explanation of the methodology, including all pre-analytical methods for processing of specimens.

(iv) Detailed discussion of the performance characteristics of the device for all claimed specimen types as shown by the analytical and clinical studies required under paragraphs (b)(3)(ii) and (iii) of this section, except specimen stability performance characteristics.

(v) A statement that nationally notifiable results are to be reported to public health authorities in accordance with local, state, and federal law.

(3) Design verification and validation must include:

(i) A detailed device description (e.g., all device parts, control elements incorporated into the test procedure, reagents required but not provided, the principle of device operation and test methodology), and the computational path from collected raw data to reported result (e.g., how collected raw signals are converted into a reported result).

(ii) Detailed documentation of analytical studies, including those demonstrating Limit of Detection (LoD), inclusivity, cross-reactivity, microbial interference, interfering substances, competitive inhibition, carryover/cross contamination, specimen stability, within lab precision, and reproducibility, as appropriate.

(iii) Detailed documentation and performance results from a clinical study that includes prospective (sequentially collected) samples for each claimed specimen type and, when determined to be appropriate by FDA,

additional characterized clinical samples. The study must be performed on a study population consistent with the intended use population and compare the device performance to results obtained from FDA-accepted comparator methods. Documentation from the clinical studies must include the clinical study protocol (including a predefined statistical analysis plan), study report, testing results, and results of all statistical analyses.

(iv) A detailed description of the impact of any software, including software applications and hardware-based devices that incorporate software, on the device's functions.

Dated: August 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–18264 Filed 8–15–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2024–N–3356]

Medical Devices; General Hospital and Personal Use Devices; Classification of the Intravenous Catheter Force-Activated Separation Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the intravenous catheter force-activated separation 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 intravenous catheter force-activated separation 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.

DATES: This order is effective August 16, 2024. The classification was applicable on May 27, 2021.

FOR FURTHER INFORMATION CONTACT: Florencia Wilson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2458, Silver Spring,