vital signs and predict future cardiovascular status or events. This device is intended for adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

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

(1) A software description and the results of verification and validation testing based on a comprehensive hazard analysis and risk assessment must be provided, including:

(i) A full characterization of the software technical parameters, including algorithms;

(ii) A description of the expected impact of all applicable sensor acquisition hardware characteristics and associated hardware specifications;

(iii) A description of sensor data quality control measures;

(iv) A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy;

(v) A description of the expected time to patient status or clinical event for all expected outputs, accounting for differences in patient condition and environment; and

(vi) The sensitivity, specificity, positive predictive value, and negative predictive value in both percentage and number form.

(2) A scientific justification for the validity of the predictive cardiovascular indicator algorithm(s) must be provided. This justification must include verification of the algorithm calculations and validation using an independent data set.

(3) A human factors and usability engineering assessment must be provided that evaluates the risk of misinterpretation of device output.

(4) A clinical data assessment must be provided. This assessment must fulfill the following:

(i) The assessment must include a summary of the clinical data used, including source, patient demographics, and any techniques used for annotating and separating the data.

(ii) The clinical data must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified.

(iii) The assessment must demonstrate output consistency using the expected range of data sources and data quality encountered in the intended use population and environment.

(iv) The assessment must evaluate how the device output correlates with the predicted event or status.

(5) Labeling must include:

(i) A description of what the device measures and outputs to the user;

(ii) Warnings identifying sensor acquisition factors that may impact measurement results;

(iii) Guidance for interpretation of the measurements, including a statement that the output is adjunctive to other physical vital sign parameters and patient information;

(iv) A specific time or a range of times before the predicted patient status or clinical event occurs, accounting for differences in patient condition and environment;

(v) Key assumptions made during calculation of the output;

(vi) The type(s) of sensor data used, including specification of compatible sensors for data acquisition;

(vii) The expected performance of the device for all intended use populations and environments; and

(viii) Relevant characteristics of the patients studied in the clinical validation (including age, gender, race or ethnicity, and patient condition) and a summary of validation results.

Dated: February 7, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–03096 Filed 2–11–22; 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–2021–N–0994]**

## Medical Devices; General Hospital and Personal Use Devices; Classification of the Spore Test Strip

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

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is classifying the spore test strip 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 spore test strip'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 February 14, 2022. The classification was applicable on March 30, 2012.

**FOR FURTHER INFORMATION CONTACT:** Clarence Murray III, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4506, Silver Spring, MD 20993–0002, 301–796–0270, *Clarence.Murray@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

Upon request, FDA has classified the spore test strip 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. 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. 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 (PMA) 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

For this device, FDA issued an order on July 1, 2011, finding the VERIFY S40 Biological Indicator Kit 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 August 1, 2011, FDA received STERIS Corporation's request for De Novo classification of the VERIFY Spore Test Strip for S40. 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 March 30, 2012, 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 880.6887.[1] We have named the generic type of device spore test strip, and it consists of a carrier or strip with a known number of spores, at least 5 $\log_{10}$ per strip, of known resistance to a particular liquid chemical sterilant in a liquid chemical sterilant processing system. A ''no growth'' result from the spore test strip after the specified predetermined incubation period indicates that the liquid chemical sterilization process achieved the conditions necessary to kill the specified minimum number of viable spores on the test strip, which is 5 $\log_{10}$ spores/strip. It does not confirm the expected full performance of the liquid chemical sterilant processing cycle because full performance is a 6 $\log_{10}$ spore kill in a full liquid chemical sterilization cycle.

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—SPORE TEST STRIP RISKS AND MITIGATION MEASURES

| Identified risks | Mitigation measures |
|---|---|
| User handling error due to false fail spore test strip device result due to technical malfunction. | Spore strip characterization, Simulated use testing, Shelf life, and Labeling. |
| User handling error due to false pass spore test strip device result due to technical malfunction. | Spore strip characterization, Simulated use testing, Shelf life, and Labeling. |
| User handling error due to misunderstanding spore test strip device use instructions. | 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. 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. 3501–3521). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of

[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.

Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the 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 part 801, regarding labeling, have been approved under OMB control number 0910–0485.

**List of Subjects in 21 CFR Part 880**

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 880 is amended as follows:

## PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for part 880 continues to read as follows:

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

■ 2. Add § 880.6887 to subpart G to read as follows:

**§ 880.6887 Spore test strip.**

(a) *Identification.* The spore test strip consists of a carrier or strip with a known number of spores, at least 5 $\log_{10}$ per strip, of known resistance to a particular liquid chemical sterilant in a liquid chemical sterilant processing system. A ''no growth'' result from the spore test strip after the specified predetermined incubation period indicates that the liquid chemical sterilization process achieved the conditions necessary to kill the specified minimum number of viable spores on the test strip which is 5 $\log_{10}$ spores/strip; it does not confirm the expected full performance of the liquid chemical sterilant processing cycle because full performance is a 6 $\log_{10}$ spore kill in a full liquid chemical sterilization cycle.

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

(1) *Spore strip characterization.* (i) Population of viable spores on strip shall be a minimum of 5 $\log_{10}$ after physical wash off of spores from the strip by exposure to liquid chemical sterilant in the liquid chemical sterilant processing system, which should be validated over the claimed shelf life.

(ii) The resistance characteristics of the viable spores on the strip should be defined and be validated over the claimed shelf life.

(iii) The spore strip description should address the carrier material, how the spores are placed on the carrier, and whether there is any feature that minimizes spore wash off. Bacteriostasis of the spore strip materials should be evaluated.

(iv) Incubation time for viable spores on the strip should be validated under the specified incubation conditions over the claimed shelf life.

(2) *Simulated Use Testing.* Simulated use testing should demonstrate performance of spore test strip in liquid chemical sterilant/high level disinfectant under worst case in use conditions over the claimed shelf life.

(3) *Labeling.* Labeling should specify appropriate instructions, warnings, cautions, limitations, and information relating to viable spore population, resistance characteristics, and interpretation of a ''no growth'' result.

Dated: February 7, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–03104 Filed 2–11–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

## 24 CFR Parts 14, 17, 20, 26, 28, 30, 81, 103, 180, and 570

**[Docket No. FR–6285–F–01]**

## HUD Office of Hearings and Appeals

**AGENCY:** Office of Hearings and Appeals, HUD.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends HUD's regulations regarding HUD's Office of Hearings and Appeals (OHA). This rule makes conforming changes to HUD regulations to reflect the office's proper title, to remove references to the terminated HUD Board of Contract Appeals, and to add a reference to recent Supreme Court precedent regarding the proper appointment procedure for administrative law judges and administrative judges.

**DATES:** *Effective* March 16, 2022.

**FOR FURTHER INFORMATION CONTACT:** J. Jeremiah Mahoney, Chief Administrative Law Judge, Office of Hearings and Appeals, Department of Housing and Urban Development, 451 7th Street SW, Room B–133, Washington, DC 20410, 202–254–0000 (not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the Federal Relay Service at 800–877–8339 (toll-free number).

**SUPPLEMENTARY INFORMATION:**

### I. Background

The HUD Office of Hearings and Appeals (OHA) is an independent judicial office within HUD's Office of the Secretary. The OHA is headed by the Chief Administrative Law Judge, who supervises the judges and the professional and administrative support staffs.

Each Administrative Judge and each Administrative Law Judge is appointed by the HUD Secretary as an Officer of the United States. The Judges also may be appointed through contracts with other U.S. Department heads and Federal Agency heads to conduct hearings and issue decisions on matters before their respective agencies.

The OHA Judges function as independent and impartial triers of fact responsible for presiding over adversarial hearings, and adjudicating appeals, based upon alleged violations of Federal statutes or their implementing regulations.

Hearing procedures are established by agency regulations and are guided by the rules applicable to trials in a U.S. district court. In each case, the judge makes an impartial decision based upon the law, and the facts established by the evidence.

### II. This Final Rule

This final rule updates HUD's regulations in 24 CFR parts 14, 17, 20, 26, 28, 30, 81, 103, 180, and 570, to reflect that the office's title is ''Office of Hearings and Appeals,'' as changed by the HUD Secretary. These HUD regulations contain outdated references to the ''Office of Administrative Law Judges,'' ''Office of Appeals,'' and ''Board of Contract Appeals.'' This final rule updates HUD regulations throughout Title 24 to reflect these changes. While this final rule updates those sections of Title 24 that use outdated language that also implicate the hearing procedures at 24 CFR part 180, there are other sections of Title 24 that rely on the hearing procedures at 24 CFR part 180, which do not require the conforming amendments made by this final rule, including 24 CFR parts 1, 3, 6, 8, and 146. These sections of Title 24 implement federal civil rights statutes, which continue to rely on 24 CFR part 180 for administrative enforcement procedures.