number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC on February 22, 2019.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 25 April 2019

Miami, FL, Miami Intl, ILS OR LOC RWY 9, Amdt 10C
Calhoun, GA, Tom B. David Fld, LOC–A, Orig-A, CANCELLED
Plymouth, IN, Plymouth Muni, RNAV (GPS) RWY 10, Orig-A
Plymouth, IN, Plymouth Muni, VOR RWY 10, Amdt 12A
Plymouth, IN, Plymouth Muni, VOR RWY 28, Amdt 11A
Hardinsburg, KY, Breckinridge County, RNAV (GPS) RWY 10, Orig
Hardinsburg, KY, Breckinridge County, RNAV (GPS) RWY 28, Orig
Hardinsburg, KY, Breckinridge County, Takeoff Minimums and Obstacle DP, Orig
Boston, MA, General Edward Lawrence Logan Intl, ILS OR LOC RWY 4R, ILS RWY 4R SA CAT I, ILS RWY 4R CAT II, ILS RWY 4R CAT III, Amdt 11
Boston, MA, General Edward Lawrence Logan Intl, ILS OR LOC RWY 15R, Amdt 2
Boston, MA, General Edward Lawrence Logan Intl, ILS OR LOC RWY 27, Amdt 3
Boston, MA, General Edward Lawrence Logan Intl, RNAV (GPS) RWY 4R, Amdt 3
Boston, MA, General Edward Lawrence Logan Intl, RNAV (GPS) RWY 15R, Amdt 2
Boston, MA, General Edward Lawrence Logan Intl, RNAV (GPS) RWY 27, Amdt 1
Grand Rapids, MN, Grand Rapids/Itasca Co-Gordon Newstrom Fld, RNAV (GPS) RWY 34, Orig-C
Engelhard, NC, Hyde County, RNAV (GPS) RWY 11, Orig
Engelhard, NC, Hyde County, Takeoff Minimums and Obstacle DP, Orig
Clovis, NM, Clovis Muni, RNAV (GPS) RWY 30, Orig-A
East Hampton, NY, East Hampton, VOR–A, Amdt 11B, CANCELLED
Ellenville, NY, Joseph Y Resnick, GPS RWY 4, Orig, CANCELLED
Ellenville, NY, Joseph Y Resnick, GPS RWY 22, Orig, CANCELLED
Ellenville, NY, Joseph Y Resnick, RNAV (GPS) RWY 4, Orig
Ellenville, NY, Joseph Y Resnick, RNAV (GPS) RWY 22, Orig
Hazelton, PA, Hazelton Rgnl, LOC RWY 28, Amdt 9
Hazelton, PA, Hazelton Rgnl, RNAV (GPS) RWY 10, Amdt 3
Hazelton, PA, Hazelton Rgnl, RNAV (GPS) RWY 28, Amdt 2
Honey Grove, PA, Stottle Memorial, COPTER RNAV (GPS) 086, Orig, CANCELLED

Rescinded: On February 20, 2019 (84 FR 4996), the FAA published an Amendment in Docket No. 31238, Amdt No. 3839, to Part 97 of the Federal Aviation Regulations under sections 97.29 and 97.37. The following entries for Key West, FL, and Pierre, SD, effective April 25, 2019, are hereby rescinded in their entirety:

Key West, FL, Key West Intl, Takeoff Minimums and Obstacle DP, Amdt 2
Pierre, SD, Pierre Rgnl, ILS OR LOC RWY 31, Amdt 12D

[FR Doc. 2019–04648 Filed 3–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2019–N–0360]

Medical Devices; Immunology and Microbiology Devices; Classification of the Device To Detect and Identify Microorganisms and Associated Resistance Marker Nucleic Acids Directly in Respiratory Specimens

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 microorganisms and associated resistance marker nucleic acids directly in respiratory specimens 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 microorganisms and associated resistance marker nucleic acids directly in respiratory specimens 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 March 14, 2019. The classification was applicable on April 3, 2018.

FOR FURTHER INFORMATION CONTACT: Dina Jerebitski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4450, Silver Spring, MD 20993–0002, 301–796–4221, *Dina.Jerebitski@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the device to detect and identify microorganisms and associated resistance marker nucleic acids directly in respiratory specimens 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 for premarket notification under section 510(k) (21 U.S.C. 360(k)) of the FD&C

Act and Part 807 (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 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 510(k) process, when necessary, to market their device.

II. De Novo Classification

On September 11, 2017, Curetis GmbH submitted a request for De Novo classification of the Unyvero LRT Application. 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 April 3, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 866.3985. We have named the generic type of device ''device to detect and identify microorganisms and associated resistance marker nucleic acids directly in respiratory specimens,'' and it is identified as an in vitro diagnostic device intended for the detection and identification of microorganisms and associated resistance markers in respiratory specimens collected from patients with signs or symptoms of respiratory infection. The device is intended to aid in the diagnosis of respiratory infection in conjunction with clinical signs and symptoms and other laboratory findings. These devices do not provide confirmation of antibiotic susceptibility since mechanisms of resistance may exist other than those detected by 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—DEVICE TO DETECT AND IDENTIFY MICROORGANISMS AND ASSOCIATED RESISTANCE MARKER NUCLEIC ACIDS DIRECTLY IN RESPIRATORY SPECIMENS 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.	General Controls and Special Controls (1) (21 CFR 866.3985(b)(1)), (2) (21 CFR 866.3985(b)(2)), (3) (21 CFR 866.3985(b)(3)), and (4) (21 CFR 866.3985(b)(4)).
Failure to correctly interpret test results	General Controls and Special Controls (1) (21 CFR 866.3985(b)(1)), (2)(iii) (21 CFR 866.3985(b)(2)(iii)), (2)(iv) (21 CFR 866.3985(b)(2)(iv)), (2)(v) (21 CFR 866.3985(b)(2)(v)), (2)(vi) (21 CFR 866.3985(b)(2)(vi)), (2)(vii) (21 CFR 866.3985(b)(2)(vii)), (2)(viii) (21 CFR 866.3985(b)(2)(viii)), and (3) (21 CFR 866.3985(b)(3)).
Failure to correctly operate the instrument	General Controls and Special Controls (1) (21 CFR 866.3985(b)(1)), (2)(i) (21 CFR 866.3985(b)(2)(i)), (4)(ii) (21 CFR 866.3985(b)(4)(ii)), (4)(iii) (21 CFR 866.3985(b)(4)(iii)), and (4)(iv) (21 CFR 866.3985(b)(4)(iv)).

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).

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. 3501–3520). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 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 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, 360*l,* 371.

■ 2. Add § 866.3985 to subpart D to read as follows:

§ 866.3985 Device to detect and identify microorganisms and associated resistance marker nucleic acids directly in respiratory specimens.

(a) *Identification.* A device to detect and identify microorganisms and associated resistance marker nucleic acids directly from respiratory specimens is an in vitro diagnostic device intended for the detection and identification of microorganisms and associated resistance markers in respiratory specimens collected from patients with signs or symptoms of respiratory infection. The device is intended to aid in the diagnosis of respiratory infection in conjunction with clinical signs and symptoms and other laboratory findings. These devices do not provide confirmation of antibiotic susceptibility since mechanisms of resistance may exist other than those detected by the device.

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

(1) The intended use for the 21 CFR 809.10 labeling must include a detailed description of what the device detects, the type of results provided to the user, the clinical indications appropriate for test use, and the specific population(s) for which the device is intended.

(2) The 21 CFR 809.10(b) labeling must include:

(i) A detailed device description, including all device components, control elements incorporated into the test procedure, instrument requirements, ancillary reagents required but not provided, and a detailed explanation of the methodology, including all pre-analytical methods for processing of specimens.

(ii) Performance characteristics from analytical studies, including, but not limited to, limit of detection, inclusivity, reproducibility, cross reactivity, interfering substances, competitive inhibition, carryover/cross contamination, specimen stability, and linearity, as applicable.

(iii) A limiting statement that the device is intended to be used in conjunction with clinical history, signs and symptoms, and results of other diagnostic tests, including culture and antimicrobial susceptibility testing.

(iv) A detailed explanation of the interpretation of test results for clinical specimens and acceptance criteria for any quality control testing.

(v) A limiting statement that negative results for microorganisms do not preclude the possibility of infection, and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

(vi) If applicable, a limiting statement that detected microorganisms may not be the cause of lower respiratory tract infection and may be indicative of colonizing or normal respiratory flora.

(vii) If applicable, a limiting statement that detection of resistance markers cannot be definitively linked to specific microorganisms and that the source of a detected resistance marker may be an organism not detected by the assay, including colonizing flora.

(viii) If applicable, a limiting statement that detection of antibiotic resistance markers may not correlate with phenotypic gene expression.

(3) The 21 CFR 809.10(b) labeling and any test report generated by the device must include a limiting statement that negative results for resistance markers do not indicate susceptibility of detected microorganisms.

(4) Design verification and validation must include:

(i) Performance characteristics from clinical studies that include prospective (sequential) samples and, if appropriate, additional characterized 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 an FDA accepted reference method and/or FDA accepted comparator method, as appropriate. Results from the clinical studies must include the clinical study protocol (including predefined statistical analysis plan, if applicable), clinical study report, and results of all statistical analyses.

(ii) A detailed device description including the following:

(A) Thorough description of the assay methodology including, but not limited to, primer/probe sequences, primer/probe design, and rationale for target sequence selection, as applicable.

(B) Algorithm used to generate a final result from raw data (*e.g.,* how raw signals are converted into a reported result).

(iii) A detailed description of device software, including, but not limited to, validation activities and outcomes.

(iv) As part of the risk management activities, an appropriate end user device training program must be offered as an effort to mitigate the risk of failure from user error.

Dated: March 8, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04719 Filed 3–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2019–N–0396]

Medical Devices; Neurological Devices; Classification of the Transcranial Magnetic Stimulation System for Neurological and Psychiatric Disorders and Conditions

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions into class II (special controls). The