TABLE 1—CLOZAPINE TEST SYSTEM RISKS AND MITIGATION MEASURES—Continued

Identified risks to health	Mitigation measures
Incorrect interpretation of test results	Certain design verification and validation activities and Certain labeling information.

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 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 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 862

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 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

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

■ 2. Add § 862.3245 to subpart D to read as follows:

§ 862.3245 Clozapine test system.

(a) *Identification.* A clozapine test system is a device intended to measure clozapine in human specimens. Measurements obtained by this device are used in monitoring levels of clozapine to ensure appropriate therapy in patients with treatment-resistant schizophrenia.

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

(1) Design verification and validation must include the following:

(i) Precision study data that demonstrates precision that is clinically appropriate, as determined by FDA, for the clozapine test system. Precision studies must include a minimum of three samples containing different concentrations of clozapine including near medical decision points and throughout the expected therapeutic range of clozapine. Samples near the medical decision points must be clinical specimens collected from patients taking clozapine;

(ii) Method comparison data that demonstrates accuracy that is clinically acceptable, as determined by FDA, for the clozapine test system;

(iii) Data from studies that demonstrate that the device is free from clinically significant interference, as determined by FDA, from commonly co-administered medications that are used in patients with treatment-resistant schizophrenia; and

(iv) Data from studies that demonstrate that the device is free from clinically significant cross-reactivity, as determined by FDA, from major circulating metabolites found in the intended use population.

(2) The labeling required under § 809.10 of this chapter must include a limiting statement conveying that the assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures and that results from the assay alone should not be used in making treatment decisions.

Dated: September 10, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20895 Filed 9–13–24; 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–4061]

Medical Devices; Immunology and Microbiology Devices; Classification of the Device To Detect or Measure Nucleic Acid From Viruses Associated With Head and Neck Cancers

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 or measure nucleic acid from viruses associated with head and neck cancers 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 or measure nucleic acid from viruses associated with head and neck cancers' 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 September 16, 2024. The classification was applicable on May 11, 2020.

FOR FURTHER INFORMATION CONTACT: Kim Davis, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3220, Silver Spring, MD 20993–0002, 301–796–1049, *Kim.Davis@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the device to detect or measure nucleic acid from viruses associated with head and neck cancers as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness.

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 part 860, subpart D (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 510(k) process, when necessary, to market their device.

II. De Novo Classification

On June 24, 2019, FDA received Advance Sentry Corp.'s request for De Novo classification of the NP Screen. 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 May 11, 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 866.3236.[1] We have named the generic type of device as device to detect or measure nucleic acid from viruses associated with head and neck cancers, and it is identified as an in vitro diagnostic test for prescription use in the detection of viral nucleic acid in nasopharyngeal or oropharyngeal cellular specimens from patients with signs and symptoms of head and neck cancer. The test result is intended to be used in conjunction with other clinical information to aid in assessing the clinical status of virus-associated head and neck cancers and/or the likelihood that head and neck cancer is present.

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 OR MEASURE NUCLEIC ACID FROM VIRUSES ASSOCIATED WITH HEAD AND NECK CANCERS RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
False test results	Use of certain specimen collection and transport devices; Certain labeling information; and Certain design verification and validation.
Failure to correctly interpret the test results	Certain labeling information.

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

[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.

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 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 § 866.3236 to subpart D to read as follows:

§ 866.3236 Device to detect or measure nucleic acid from viruses associated with head and neck cancers.

(a) *Identification.* A device to detect or measure nucleic acid from viruses associated with head and neck cancers is an in vitro diagnostic test for prescription use in the detection of viral nucleic acid in nasopharyngeal or oropharyngeal cellular specimens from patients with signs and symptoms of head and neck cancer. The test result is intended to be used in conjunction with other clinical information to aid in assessing the clinical status of virus-associated head and neck cancers and/or the likelihood that head and neck cancer is present.

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

(1) Any device used for specimen collection and transport must be FDA-cleared, -approved, or -classified as 510(k) exempt (standalone or as part of a test system) for the collection of human specimens; 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, as determined to be appropriate by FDA:

(i) An intended use statement that includes the following:

(A) The analyte(s) detected by the device;

(B) Data output of the device (qualitative, semiquantitative, or quantitative);

(C) The specimen types with which the device is intended for use;

(D) The clinical indications appropriate for test use (*e.g.,* in conjunction with endoscopy);

(E) The intended use populations (*e.g.,* signs and symptoms, ethnicity); and

(F) The intended use location(s) (*e.g.,* specific name and location of testing facility or facilities).

(ii) A detailed device description, including reagents, instruments, ancillary materials, specimen collection and transport devices, controls, and a detailed explanation of the methodology, including all pre-analytical methods for processing of specimens.

(iii) A detailed explanation of the interpretation of results.

(iv) Limiting statements indicating:

(A) The device is not intended for use in screening for head and neck cancer in asymptomatic populations.

(B) Results of the device are not predictive of a patient's future risk of head and neck cancer.

(C) Patients who test negative for the virus should be managed in accordance with the standard of care, based on the assessment of endoscopy and/or other clinical information by a licensed healthcare professional.

(D) Results of the device are not intended to be used as the sole basis for determining the need for biopsy or for any other patient management decision.

(3) Design verification and validation must include the following:

(i) A detailed device description including pre-analytical specimen processing, assay technology, target region, primer/probe sequences, reagents, controls, instrument requirements, and the computational path from collected raw data to reported result.

(ii) Detailed documentation and results from analytical performance studies, including characterization of the cutoff(s), limit of detection, limit of quantitation, precision (including multisite reproducibility, if applicable), inclusivity, cross-reactivity, interference, carryover/cross-contamination, reagent stability, and specimen/sample stability, as determined to be appropriate by FDA.

(iii) Detailed documentation of a clinical performance study that includes patients from the intended use population, including the clinical study protocol, with a predefined statistical analysis plan, and a clinical study report with testing results and results of all statistical analyses.

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

Dated: September 10, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20896 Filed 9–13–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2024–N–4082]

Medical Devices; Therapeutic Devices; Classification of the Pediatric Continuous Renal Replacement Therapy System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is