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]

BILLING CODE 4164–01–P

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

classifying the pediatric continuous renal replacement therapy system 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 pediatric continuous renal replacement therapy system'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 September 16, 2024. The classification was applicable on April 29, 2020.

FOR FURTHER INFORMATION CONTACT: Gema Gonzalez, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2530, Silver Spring, MD 20993–0002, 301–796–6519, *Gema.Gonzalez@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the pediatric continuous renal replacement therapy system 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 October 9, 2018, FDA received Medtronic, Inc.'s request for De Novo classification of the CARPEDIEM System. 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 29, 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 876.5861.[1] We have named the generic type of device pediatric continuous renal replacement therapy system, and it is identified as a device intended for use as an artificial kidney system for the management of pediatric patients with acute kidney injury and/or fluid overload by performing such therapies as hemodialysis, hemofiltration, hemodiafiltration, and isolated ultrafiltration. Using a hemodialyzer with a semipermeable membrane, the hemodialysis system removes toxins or excess fluid from the patient's blood using the principles of convection (via ultrafiltration) and/or diffusion (via a concentration gradient in dialysate). The hemodialysis delivery machine, with an automated ultrafiltration controller, controls and monitors the parameters related to this processing, including the rate at which blood and dialysate are pumped through the system, and the rate at which fluid is removed from the patient. During treatment, a patient's blood is circulated through the blood tubing set connected to the hemodialyzer's blood compartment. Blood access devices and accessories for hemodialysis required for the prescribed treatment are regulated under 21 CFR 876.5540.

FDA has identified the following risks to health associated specifically with this type of device and the measures

[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.

required to mitigate these risks in table 1.

TABLE 1—PEDIATRIC CONTINUOUS RENAL REPLACEMENT THERAPY SYSTEM RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation, Pyrogenicity testing, and Non-clinical performance testing.
Death	Labeling, Clinical performance testing, and Usability testing.
Infection	Labeling, Reprocessing validation, Pyrogenicity testing, Shelf life testing, and Usability testing.
Inadequate or incomplete treatment	Non-clinical performance testing; Clinical performance testing; Labeling; Shelf-life testing; Usability testing; and Software verification, validation, and hazard analysis.
Clearance of essential blood substances or medications	Non-clinical performance testing; Clinical performance testing; Labeling; Shelf-life testing; Usability testing; and Software verification, validation, and hazard analysis.
Blood loss or blood cell destruction	Non-clinical performance testing; Clinical performance testing; Labeling; Shelf-life testing; and Software verification, validation, and hazard analysis.
Thermal injury	Non-clinical performance testing; Clinical performance testing; Labeling; Shelf-life testing; Usability testing; and Software verification, validation, and hazard analysis.
Blood leak into the dialysis fluid	Non-clinical performance testing; Clinical performance testing; Labeling; Shelf-life testing; and Software verification, validation, and hazard analysis.
Fluid imbalance	Non-clinical performance testing; Clinical performance testing; Labeling; Shelf-life testing; and Software verification, validation, and hazard analysis.
Air embolism	Non-clinical performance testing; Clinical performance testing; Labeling; Shelf-life testing; Usability testing; and Software verification, validation, and hazard analysis.
Fluid pump(s) reversal resulting in air infusion via the arterial bloodline	Non-clinical performance testing; Clinical performance testing; Labeling; Shelf-life testing; Usability testing; and Software, verification, validation, and hazard analysis.
Electrical shock	Electrical safety testing.
Electromagnetic interference with other devices/equipment	Electromagnetic compatibility (EMC) testing.

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 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 part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 876

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 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

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

■ 2. Add § 876.5861 to subpart F to read as follows:

§ 876.5861 Pediatric continuous renal replacement therapy system.

(a) *Identification.* A pediatric continuous renal replacement therapy hemodialysis system is a device intended for use as an artificial kidney system for the management of pediatric patients with acute kidney injury and/or fluid overload by performing such therapies as hemodialysis, hemofiltration, hemodiafiltration, and isolated ultrafiltration. Using a hemodialyzer with a semipermeable membrane, the hemodialysis system removes toxins or excess fluid from the patient's blood using the principles of convection (via ultrafiltration) and/or diffusion (via a concentration gradient in dialysate). The hemodialysis delivery machine, with an automated ultrafiltration controller, controls and monitors the parameters related to this processing, including the rate at which blood and dialysate are pumped through the system, and the rate at which fluid is removed from the patient. During treatment, a patient's blood is circulated through the blood tubing set connected to the hemodialyzer's blood compartment. Blood access devices and accessories for hemodialysis required for the prescribed treatment are regulated under § 876.5540.

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

(1) Clinical performance testing must confirm the safety and the accuracy, precision, and reproducibility of the non-clinical performance data under anticipated conditions of use.

(2) Usability testing must demonstrate that a user can correctly use the hemodialysis delivery device based solely on reading the instructions for use.

(3) Non-clinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Hemodialysis delivery system performance testing must include:

(A) Fluid flow accuracy testing; and

(B) Functional testing of system components including sensors, pumps, and scales to acceptance criteria.

(ii) Hemodialyzer performance testing must include:

(A) Ultrafiltration;

(B) Blood and dialysate pressure drop;

(C) Clearance rates;

(D) Sieving coefficients;

(E) Mechanical hemolysis;

(F) Structural integrity;

(G) Blood compartment integrity;

(H) Volume of the blood compartment; and

(I) Chemical analysis of the dialyzer membrane.

(iii) Blood tubing set performance testing must include:

(A) Pressure leak testing;

(B) Worst-case endurance testing;

(C) Priming volume assessment;

(D) Tensile testing of joints and materials of all tubing segments;

(E) Pressure transducer leak testing;

(F) Clamp occlusion;

(G) Mechanical hemolysis; and

(H) Kink testing.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Performance data must demonstrate the electromagnetic compatibility (EMC), electrical safety, and wireless compatibility of the device.

(6) The tissue-contacting components of the device must be demonstrated to be biocompatible.

(7) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(8) Performance data must validate the reprocessing instructions for the reusable components of the device.

(9) The patient-contacting components of the device must be demonstrated to be non-pyrogenic.

(10) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(11) Device labeling must include:

(i) Hemodialysis delivery system labeling must provide detailed information regarding the safe use of the dialysis machine, including:

(A) Overall description of the device and individual components or accessories labeled for use with the delivery system;

(B) Description of the safety-related components included in the system;

(C) Identification of operational parameters;

(D) Alarms and troubleshooting information;

(E) Cleaning, disinfection, and preventative maintenance procedures; and

(F) A statement that the device is intended for use by operators trained in the administration of continuous renal replacement therapy and in the management of its complications.

(ii) Hemodialyzer labeling must include:

(A) Description of compatibility;

(B) Shelf life;

(C) Storage conditions;

(D) Instructions for the preparation of the hemodialyzer, initiation of dialysis, troubleshooting, and discontinuance of dialysis;

(E) Membrane surface area, priming (blood) volume, maximum transmembrane pressure, maximum blood flow and maximum dialysate rate for each model;

(F) Summary of the in vitro performance data; and

(G) A non-pyrogenic statement.

(iii) Blood tubing set labeling must provide detailed information regarding the safe use of the device, including:

(A) Description of compatibility;

(B) Shelf life;

(C) Storage conditions;

(D) Identification of the components in the package;

(E) Total length of the arterial and venous tubing sets;

(F) Outer diameter (OD) of the pump segment;

(G) Priming volume;

(H) Identification of the hemodialysis delivery systems which are compatible with the blood tubing set;

(I) Identification of the largest gauge needle that can be used with the injection port, if applicable; and

(J) Identification of the maximum operating pressures for the transducer protectors.

Dated: September 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20999 Filed 9–13–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 214

[Docket No. FR–6388–F–02]

RIN 2502–AJ70

Modernizing the Delivery of Housing Counseling Services

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: The Department of Housing and Urban Development (HUD) is issuing this final rule to update HUD's regulations that require participating agencies to provide in-person counseling to clients that prefer this format to reflect advances in technology, align with client engagement preferences, and preserve consumer protections. The final rule amends HUD's regulations to allow housing counseling agencies to use alternative communication methods, including virtual meeting tools, in lieu of providing in-person services. Participating agencies that choose not to provide in-person services are required to refer clients to local providers that provide such services, when requested. After considering public comments received in response to the proposed rule HUD published on October 25, 2023, this final rule adopts the proposed rule without change.

DATES: Effective October 16, 2024.

FOR FURTHER INFORMATION CONTACT: David Valdez, Senior Housing Program Specialist, Department of Housing and Urban Development, 1331 Lamar St. Suite 550, Houston, TX 77002, telephone 713–718–3178 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 106 of the Housing and Urban Development Act of 1968 (12 U.S.C. 1701x) (Section 106) authorizes HUD's Housing Counseling program (see Sections 106(a)(1)(iii) and 106(a)(2)). On October 25, 2023, HUD published the ''Modernizing the Delivery of Housing Counseling Services'' proposed rule (''the proposed rule'') in the **Federal Register**, at 88 FR 73298, to revise the current regulations governing HUD's Housing Counseling program to align with client engagement preferences, and to preserve consumer protections, while leaving in place existing guardrails that ensure participating agencies demonstrate knowledge and a connection to the community they serve, whether they choose to do so by providing virtual, in-person, or hybrid services.

As described in the proposed rule, on September 28, 2007, HUD published a final rule titled, ''Housing Counseling Program,'' at 72 FR 55637, which established regulations for HUD's Housing Counseling program (see 24 CFR 214.103(l) and 24 CFR 214.300, in particular). These regulations had not been amended since they were established. Section 214.300(a)(3) required agencies that provide housing counseling services to provide in-person counseling services at one of the agency's facilities or an alternate location to clients that preferred that format. When this requirement was adopted, housing counseling and education were primarily conducted in-person and the conventional wisdom was that in-person service was the most effective service delivery method. However, alternatives to in-person service have also proven to be effective.

In 2020, due to ongoing public health concerns around the spread of Coronavirus Disease 2019 (COVID–19), HUD issued a Temporary Partial Waiver of 24 CFR 214.300(a)(3), *In-Person Housing Counseling Requirement,* that allowed housing counseling agencies to utilize alternative methods to conduct housing counseling and education with clients in lieu of meeting in-person. Feedback received regarding this waiver indicated that these alternative methods were more practical, cost-effective, and accessible, and did not lead to adverse compliance issues or negative financial impacts. This feedback, increased consumer preference for virtual service delivery, and reduced burdens and costs for participating agencies, all weigh in favor of modernizing the current regulations.

HUD's proposed rule, then, proposed amending the regulations such that participating agencies must maintain at least one facility and may provide remote housing counseling. Additional details about the proposed rule may be found at 88 FR 73298 (October 25, 2023).

II. Final Rule

This final rule adopts the proposed rule without change. This rule will help reduce the costs of providing housing counseling by allowing participating agencies to provide housing counseling services at a facility or at an alternate location, via telephone, or via collaborative online software. All facilities must have an identified, private space available for the provision of counseling services, whether those services are in-person or virtual, and housing counseling agencies that do not provide in-person counseling services must refer clients to agencies that provide in-person counseling services upon a client's request. This rule does not change the requirements that every housing counseling agency must continue to meet for HUD approval as a counseling agency, regardless of the setting or format of housing counseling services, including having functioned for at least one year in the geographical area(s) the agency identified in its housing counseling work plan, having sufficient resources to implement that proposed work plan, and being able to demonstrate knowledge of local housing markets and community resources.

III. The Public Comments

HUD received 33 public comments on the proposed rule from various interested parties, including housing finance companies, housing counseling service agencies (including HUD-approved agencies), housing counselors, state housing agency associations, community development and other nonprofit organizations, and other individuals and entities.

Support for the Rule

Most commenters supported HUD's proposal and supported providing individuals with options for different formats and types of housing counseling services, including telephonic and online services. Some commenters cited general benefits such as increased