April 29, 2020

Bellco S.r.l.
% Michele Gust
Sr Regulatory Affairs Director
Medtronic, Inc
710 Medtronic Parkway
Minneapolis, MN 55432

Re: DEN180055
Trade/Device Name: CARPEDIEM System
Regulation Number: 21 CFR 876.5861
Regulation Name: Pediatric continuous renal replacement therapy system
Regulatory Class: II
Product Code: QIR
Dated: October 5, 2018
Received: October 9, 2018

Dear Michele Gust:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the CARPEDIEM System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The CARPEDIEM System is indicated for use in acute kidney injury or fluid overloaded patients requiring hemodialysis or hemofiltration therapy. It is intended to provide continuous renal replacement therapy (CRRT) to patients weighing between 2.5 and 10 kilograms.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the CARPEDIEM System, and substantially equivalent devices of this generic type, into Class II under the generic name Pediatric Continuous Renal Replacement Therapy System.

FDA identifies this generic type of device as:

> **Pediatric continuous renal replacement therapy system**. 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 21 CFR § 876.5540.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On October 9, 2018, FDA received your De Novo requesting classification of the CARPEDIEM System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the CARPEDIEM System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the CARPEDIEM System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	**Mitigation Measures**
Adverse tissue reaction	Biocompatibility evaluation Pyrogenicity testing Non-clinical performance testing
Death	Labeling Clinical performance testing Usability testing
Infection	Labeling Reprocessing validation Pyrogenicity testing Shelf life testing Usability testing
Inadequate or incomplete treatment	Non-clinical performance testing Clinical performance testing Labeling Software verification, validation, and hazard analysis Shelf-life testing

	Usability testing
Clearance of essential blood substances or medications	Non-clinical performance testing Clinical performance testing Labeling Software verification, validation, and hazard analysis Shelf-life testing Usability testing
Blood loss or blood cell destruction	Non-clinical performance testing Clinical performance testing Labeling Software verification, validation, and hazard analysis Shelf-life testing
Thermal injury	Non-clinical performance testing Clinical performance testing Labeling Software verification, validation, and hazard analysis Shelf-life testing Usability testing
Blood leak into the dialysis fluid	Non-clinical performance testing Clinical performance testing Labeling Software verification, validation, and hazard analysis Shelf-life testing
Fluid imbalance	Non-clinical performance testing Clinical performance testing Labeling Software verification, validation, and hazard analysis Shelf-life testing
Air embolism	Non-clinical performance testing Clinical performance testing Labeling Software verification, validation, and hazard analysis Shelf-life testing Usability testing
Fluid pump(s) reversal resulting in air infusion via the arterial bloodline	Non-clinical performance testing Clinical performance testing Labeling Software verification, validation, and hazard analysis Shelf-life testing Usability testing
Electrical shock	Electrical safety testing
Electromagnetic interference with other devices/equipment	Electromagnetic compatibility (EMC) testing

In combination with the general controls of the FD&C Act, the pediatric continuous renal replacement therapy system is subject to the following special controls:

(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.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the pediatric continuous renal replacement therapy system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Dr. Carolyn Neuland, at 301-796-6523

Sincerely,

Benjamin R. Fisher -S

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Director
OHT3: Office of GastroRenal, ObGyn,
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