October 15, 2021

Institut Georges Lopez
Matthieu Prouteau
Director of Quality Affairs and Regulatory Affairs
Parc Tertiaire du Bois Dieu
RN6 - 1 Allee des Chevreuils
Lissieu, 69380
FRANCE

Re: K211224
Trade/Device Name: RM4 control unit
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: KDN
Dated: September 14, 2021
Received: September 17, 2021

Dear Matthieu Prouteau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

for Glenn B. Bell, Ph.D.
Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211224

Device Name
RM4 control unit

Indications for Use *(Describe)*
The RM4 control unit, as part of the RM4 Kidney Perfusion System is intended to be used for the pulsatile hypothermic machine perfusion of kidneys for preservation and eventual transplantation into a recipient only in healthcare professional environment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

[As Required by 21 CFR 807.92(c)]

Written on April, 20 2021

Manufacturer:

Institut Georges Lopez (IGL)
Parc Tertiaire du Bois Dieu
RN6 – 1 allée des Chevreuils
69380 Lissieu, France
Telephone: +33 437 646 332
Official Contact: Matthieu Prouteau – Director of Quality Affairs and Regulatory Affairs

Device Information

Trade Name:	RM4 control unit
Common Name:	System, Perfusion, Kidney
Regulation Description:	Isolated kidney perfusion and transport system and accessories
Regulation Number:	21 CFR 876.5880
Class:	Class II
Product Code:	KDN
Premarket Review:	Renal, Gastrointestinal, Obesity and Transplant Devices (DHT3A)
Review Panel:	Gastroenterology/Urology

Predicate Device Identification

RM3 Renal Preservation System – Control Unit (Waters Instruments, Inc.) – K971571
(The predicate device has not been subject to a design-related recall)

Device Description

The RM4 Control Unit controls kidney perfusion of hypothermic physiologic solutions and monitors, displays, trends, and saves the perfusion parameters. The RM4 Control Unit is part of the RM4 Kidney Perfusion System (RM4), which is a lightweight and compact renal perfusion system intended to provide controlled perfusion of a hypothermic physiologic solution for the preservation of donor kidney organs before transplantation into the recipient. The RM4 Control Unit is used with a sterile, disposable, single-use, organ cassette intended to receive one or two kidneys from the same donor. The system is provided with a power cord and a USB flash drive that contains the instructions for use, and is intended to be used with an organ cassette and accessories including an insulation cover, and various cannulas/clamps for arterial cannulation of the kidneys to the perfusate circuit into the cassette.

Indications for Use

The RM4 control unit, as part of the RM4 Kidney Perfusion System is intended to be used for the pulsatile hypothermic machine perfusion of kidneys for preservation and eventual transplantation into a recipient only in healthcare professional environment.

Comparison of Technological Characteristics

The subject device has the same intended use as the predicate device. The indications for use of the subject device were updated compared to the predicate device to better reflect the conditions of use of the device. While the indications for use statements are not identical, the conditions and environments of use of the subject device are identical to the ones of the predicate device and do not affect the determination of substantial equivalence. As a modernized version of the predicate device, the subject device has identical features and principle of operation as the predicate device. Both devices use the same disposable organ cassette and present similar technical specifications. The main differences between the subject device and the predicate device are the design and the software.

The design and internal components of the RM4 Control Unit were changed compared to the predicate RM3 Control Unit in order to optimize the dimensions and weight of the device to facilitate its manipulation, as well as to improve the performance of the device. Verification and validation testing was conducted on the subject device to ensure that these differences do not impact the safety and effectiveness of the subject device compared to the predicate device. Testing included sensors performance testing, pulsatile pump testing, cooling system testing, operational testing, bubble priming testing, power management testing, and accessories compatibility verification testing.

The software of the subject device was redesigned compared to the predicate device in order to provide a more user-friendly interface without changing the main features. Software validation was conducted to ensure that the software of the RM4 does not raise new issues of safety and effectiveness compared to the RM3.

Summary of Non-Clinical Testing

No performance standards have been established by FDA for the RM4 Control Unit. The following tests were performed to demonstrate safety based on current industry standards:

Software Verification and Validation: The software development and testing were executed according to the following standards:

- IEC 62304:2006/Amd 1:2015 *Medical device software - Software life cycle processes*
- ISO 14971:2019 *Medical devices — Application of risk management to medical devices*

Electrical Safety and Electromagnetic Compatibility: The subject device was tested for compliance to the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 *Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance*

- IEC 60601-1-2 Edition 4.0 2014-02 *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*
- IEC 62133 Edition 2.0 2012-12 *Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications [Including: Corrigendum 1 (2013)]*
- IEC 60601-1-8 Edition 2.1 2012-11 *Medical electrical equipment. General requirements for safety. Collateral standard. General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical system*

Performance Testing: The performance testing of the subject device included sensors performance testing, pulsatile pump testing, cooling system testing, operational testing, bubble priming testing, power management testing, and accessories compatibility verification testing.

The results of these tests indicate that the RM4 Control Unit is substantially equivalent to the predicate device.

Conclusion

The technological differences between the subject and predicate devices were evaluated through non-clinical testing. The results of these tests demonstrated that the subject device does not raise new issues of safety and effectiveness compared to the predicate device. The indications for use, technological characteristics, and performance characteristics of the RM4 Control Unit are assessed to be substantially equivalent to the predicate device.