April 25, 2025

Institut Georges Lopez (IGL)
Matthieu Prouteau
Director of Quality & Regulatory Affairs
Parc Tertiaire du Bois Dieu
1 Allée des Chevreuils
Lissieu, 69380
France

Re: K243998
Trade/Device Name: DCX Disposable Cassette (DCX)
Regulation Number: 21 CFR§ 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: KDN
Dated: March 27, 2025
Received: March 27, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Maura Rooney -S

Maura Rooney
Assistant 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243998

Device Name

DCX Disposable Cassette (DCX)

Indications for Use *(Describe)*

The DCX Disposable Cassette, as part of the Kidney Perfusion System, is intended to be used for the pulsatile hypothermic machine perfusion (RM4 Kidney Perfusion System) 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.

510(k) Summary

[As required by 21 CFR 807.92]

Written on December, 17 2024

I. Submitter

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France
Telephone: +33 437 646 332
Official Contact**:** Matthieu Prouteau – Director of Quality and Regulatory Affairs

II. Device Information

Trade Name:	DCX Disposable Cassette (DCX)
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

III. Predicate Device Identification

	K Number	Predicate Device Name	Manufacturer
Predicate	K211224	RM4 control unit	Institut Georges Lopez - IGL (France)

IV. Device Description

The DCX Disposable Cassette, provides a sterile fluid pathway, houses and protects the kidneys during perfusion and it has a gravity flow system which allows circulation of perfusate through the kidneys.

The kidneys are placed in an organ chamber filled with perfusate. The perfusate flows from the organ chamber to the pumphead. Then, it is pumped through the heat exchanger to the bubble trap where it is delivered to the cannulated kidney(s). The perfusate then returns to the organ chamber via the kidney vein to repeat the perfusion cycle.

The cassette can provide circulation of perfusate to one or two kidneys, attached individually or in bloc.

V. Indication for Use

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

VI. Comparaison of Technological Characteristics

The DCX Disposable Cassette and the DCM-100 Disposable Cassette used with the Kidney Perfusion system have identical technical specifications.

DCX Disposable Cassette is the new version of the DCM-100 Disposable Cassette, compatible with the RM4 Perfusion system (control unit). In order to improve the system and the condition of kidney storage, IGL develops for the new cassette, following technical characteristics:

- connection luer for perfusion accessories
- in the DCX, the oxygenation is provided directly in the organ chamber, whereas on the DCM-100 the perfusate circulates through a membrane where O_2 exchange occurs (two different means to bring oxygen to the perfusate).
- the placement of a removable partition to allow the immersion of the organ using 1L of perfusate instead of 2L of perfusate for single organ perfusion in the DCX. In DCM-100, even if it for a single perfusion, 2L of solution have to be poured inside the system.
- the number of lids. Indeed, two lids are on the DCX whereas only one lid is on the DCM-100.

Both cassettes are packaged into a primary packaging which is considered as the sterile barrier system, then sterilized with the Ethylene Oxide sterilization method and intended for single-use only. Finally, both cassettes are labeled as sterile, single use and with a 24 months shelf life.

The difference on the labelling is on the storage conditions. Indeed, the DCX is labeled with storage conditions between 2°C and 25°C with temporary 40°C outing tolerated instead of 5°C to 50°C for DCM-100. Thus, even if the storage condition of both cassettes are different, the range of temperature is similar.

Comparison with Predicate Device		
	Subject Device	**Primary Predicate Device**
	RM4 Kidney Perfusion System with DCX	RM4 Kidney Perfusion System with DCM-100 (K211224).
Regulatory Specifications		
Intended Use	Kidney storage and preservation for transplantation	Identical
Indication for Use	The DCX Disposable Cassette, as part of the Kidney Perfusion System, is intended to be used for the pulsatile hypothermic machine perfusion (RM4 Kidney Perfusion System) of kidneys for preservation and eventual transplantation into a recipient only in healthcare professional environment.	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.
Principle of Operation	Single use, disposable cassette used with a control unit which provides continuous pulsatile hypothermic physiologic perfusion	Identical
Manufacturer	Institut Geoges Lopez, France	Identical
Regulation number	21 CFR 876.5880	Identical

Comparison with Predicate Device		
	Subject Device	**Primary Predicate Device**
	RM4 Kidney Perfusion System with DCX	RM4 Kidney Perfusion System with DCM-100 (K211224).
Regulation description	Isolated kidney perfusion and transport system and accessories	Identical
Product Code	KDN	Identical
Class	Class II	Identical
Technical Specifications		
Organ Type	Kidney	Identical
Organ Capacity	One or two kidneys	Identical
Solution use to preserve the organ	PERF-GEN or equivalent solution	Identical
Transportability	Short transportation within the healthcare facility by trained personnel.	Identical
Compatible Elements	RM4 control Unit	Identical
Disposable compatible elements	Cannulas and clamps	Identical
Cassette mounting	Top of control unit	Identical
Sterilization, Shelf Life, and Storage		
Sterilization Method	Ethylene Oxide sterilization	Identical
Single use	Yes	Identical
Sterility Assurance level (SAL)	10^{-6}	Identical
Shelf life	24 months	Identical

VII. Summary of Non-Clinical Testing

No performance standard has been established by FDA for the DCX Disposable Cassette.

In order to evaluate the performance and safety of the subject device DCX. :

- The DCX is supplied sterile and non-pyrogenic in order to assure safety for transplant recipients. The validation of the sterilizing was carried out according to ISO 11135 and ISO 10993-7.
- The biomaterial safety of the DCX has been evaluated through ISO 10993 compliant testing, which included cytotoxicity test, skin sensitization test in guinea pigs, primary skin irritation, hemolysis test and acute systemic toxicity test in mice. Results of this testing, showed the DCX is safe for the intended biocontact.
- The stability testing has showed that aging of test articles at the recommended storage conditions of 2-25°C (35.6° - 77°F) does not affect the product specifications for the DCX labeled with 24 months shelf life.
- Performances tests have been performed also with perfusion accessories, and a RM4 Control Unit, in accordance with the recommendations outlined in the IFU of the subject device and in the instructions for use of the RM4 Control Units. For each test performed, the subject performs as expected and meets the requirements set for the device.

The results of these tests indicate that DCX Disposable Cassette is substantially equivalent to the

predicate devices.

VIII. 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 DCX Disposable Cassette stored for up to 24 months assessed to be substantially equivalent to the predicate device.