November 21, 2023

Cordis US Corp.
Zheng Wang
Principal Specialist, Regulatory Affairs
14201 North West 60th Avenue
Miami Lakes, Florida 33014

Re: K232573
Trade/Device Name: INFINITI™ Ambi Angiographic Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: August 24, 2023
Received: August 25, 2023

Dear Zheng Wang:

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.

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2023.11.21 13:17:34 -05'00'

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*
K232573

Device Name
INFINITI™ Ambi Angiographic Catheter

Indications for Use *(Describe)*
Cordis catheters are indicated for enabling diagnosis of various pathologies by facilitating the positioning of diagnostic devices within the coronary and peripheral vasculature.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. SUBMITTER INFORMATION (807.92(a)(1))

Manufacturer (Applicant):	Cordis US Corp. 14201 North West 60th Avenue Miami Lakes, Florida, 33014 USA Establishment Registration: 1016427
Contact Person(s)	Zheng Wang (Jessie) Principal Regulatory Affairs Specialist Cordis US Corp. 5452 Betsy Ross Drive Santa Clara, CA 95054, USA. E-mail: zheng.wang04@cordis.com Ana Lopez Sr. Manager, Regulatory Affairs Cordis US Corp. 5452 Betsy Ross Drive Santa Clara, CA 95054, USA. E-mail: ana.lopez02@cordis.com
Date Prepared:	October 24, 2023

II. DEVICE NAME (807.92(a)(2))

Proprietary Name:	INFINITI™ Ambi Angiographic Catheter (hereafter referred as INFINITI Ambi Catheter)
Common Name:	Diagnostic Intravascular Catheter
Classification:	Class II CFR Part 780.1200
Classification Panel	Cardiovascular
Product Code:	DQO

III. PREDICATE DEVICE

INFINITI™ Angiographic Catheter cleared on 9/30/1997 under K970854.

IV. DEVICE DESCRIPTION

The INFINITI Ambi Catheter is a 0.038" guidewire compatible catheter with a 3-staged braided nylon construction. The body is a braided nylon intended for torque responsiveness and stability. The proximal segment is a non-braided nylon for flexibility and shape retention. The Distal Tip is a soft, radiopaque nylon for minimal vessel cannulation.

The INFINITI Ambi product line comes in 5F and 6F size and various curve style configurations.

The device is a disposable intended for single use only. It is individually packaged and sterilized by ethylene oxide gas.

V. INTENDED/INDICATIONS FOR USE

Cordis catheters are indicated for enabling diagnosis of various pathologies by facilitating the positioning of diagnostic devices within the coronary and peripheral vasculature.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A comparison of the intended use/indications for use and technological characteristics are summarized in the table below. The minor design changes do not negatively impact the safety and effectiveness of the device.

Element	Proposed Device (INFINITI Ambi Catheter)	Predicate Device (K970854) (INFINITI Catheter)	Note
FDA Product Code	DQO	DQO	Same
Indications for Use	Cordis catheters are indicated for enabling diagnosis of various pathologies by facilitating the positioning of diagnostic devices within the coronary and peripheral vasculature.	Cordis catheters are designed to deliver radiopaque contrast medium to selected sites in the vascular system.	Different
Intended Purpose	Cordis catheters are intended to delivery radiopaque contrast medium to selected sites in the vascular system.	Not included	Added
Contra-indications	None known	None known	Same
Manufacturer	Cordis US Corp.	Cordis Corporation	Different
Manufacturing Site	Cardinal Health México 244 S de RL de CV Santiago Troncoso #808 Parque Industrial Salvarcar Ciudad Juarez, Chihuahua	Cordis Corporation 14201 North West 60th Avenue Miami Lakes, Florida 33014 USA	Different

Element	Proposed Device (INFINITI Ambi Catheter)	Predicate Device (K970854) (INFINITI Catheter)	Note
	C.P. 32574 México	Cordis Europa N.V. Postbus 38 Oosteinde 8 9300 AA Roden The Netherlands *These two sites are no longer used for the manufacturing of the Cordis products.*	
Sterilization Site	STERIS-E2 Isomedix Operations, Inc 1441 Don Haskins Drive El Paso, TX 79936 USA STERIS-E1 Isomedix Operations, Inc 1435 Isomedix Place El Paso, TX 79936 USA Sterigenics US, LLC 2400 Airport Road Santa Teresa, NM 88008 USA	For product manufactured in Miami: Isomedix, Inc. 2072 Southport Road Spartanburg, S.C. 29301-9539 Isomedix. Inc. 435 Whitney Street Northborough, MA 01532 For product manufactured in Roden: Griffith Micro Science Storkstraat 8-10 2722 NN Zoetermeer The Netherlands *These three sites are no longer used for the sterilization of the Cordis products.*	Different
Shelf Life	3 years	3 years	Same
Sterilization Method	100% Ethylene Oxide (EO)	100% Ethylene Oxide (EO)	Same
Sterility Assurance level (SAL)	10^{-6}	10^{-6}	Same
Use	Single Use	Single Use	Same
Principle of Operation			
Mechanism of Action	Facilitates the delivery of radiopaque contrast medium to selected sites in the vascular system.	Facilitates the delivery of radiopaque contrast medium to selected sites in the vascular system.	Same
Overall length	100cm, 125 cm	100cm, 125 cm	Same

Element	Proposed Device (INFINITI Ambi Catheter)		Predicate Device (K970854) (INFINITI Catheter)		Note
Proximal OD	5F – 0.066” 6F – 0.078”		5F – 0.066” 6F – 0.078”		Same
Distal Tip OD	5F – 0.066” 6F – 0.078”		5F – 0.066” 6F – 0.078”		Same
Proximal ID	5F – 0.047” 6F – 0.057”		5F – 0.047” 6F – 0.057”		Same
Distal ID	5F – 0.047”, Flush: 0.042” 6F – 0.057”, Flush: 0.042”		5F – 0.047”, Flush: 0.042” 6F – 0.057”, Flush: 0.042”		Same
Guidewire acceptance	0.038” max		0.038” max		Same
Maximum pressure	1200 psi		1200 psi		Same
Flow rate	5F 21.3	6F 35	5F 21.3	6F 35	Same
Catheter Component Materials					
Materials	Nylon and stainless-steel		Nylon and stainless-steel		Same
Product Design Characteristics					
Tip Length	1.25 inches		1.25 inches		Same
Shapes	JK 4.0, TG 4.5, JK 3.5, TG 4.0		JR/JL		New
Packaging Configuration					
Sterile Packaging	Individual package, pouch, and carton		Individual package, pouch, and carton		Same

VII. PERFORMANCE DATA

Performance testing was conducted to ensure the safety and effectiveness of the device with the minor design changes demonstrate substantial equivalence to the predicate device. No new issues of safety and effectiveness were raised with the testing performed.

Biocompatibility Testing

The INFINITI Ambi Catheter is an externally communicating device with limited contact duration (≤ 24 hours) in contact with circulating blood. Biocompatibility testing, Chemical Characterization, and Toxicological Risk Assessment on the patient contacting portions of predicate device INFINITI 5F were performed Testing was performed to meet the endpoints for evaluation from ISO 10993-1:2018 and FDA guidance: Use of International Standard ISO 10993-1, “*Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*” issued on September 4, 2020. Endpoints evaluated are as follows:

- Physical and/or Chemical Information
- Cytotoxicity – MEM Elution
- Sensitization – Guinea Pig Maximization
- Intracutaneous Irritation Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemocompatibility

Sterilization

The sterilization conditions have been validated according to ISO 11135:2014 *Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices* to provide a sterility assurance level (SAL) of 10^{-6}.

Ethylene oxide and ethylene chlorohydrin residuals meet requirements for limited exposure devices (contact < 24 hours) in accordance with ISO 10993-7:2018, *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*.

Packaging

There is no change to the packaging materials and configuration, therefore, no new packaging verification testing was required to be conducted on the subject INFINITI Ambi Catheter.

Bench Testing

The following testing was successfully completed for the INFINITI Ambi Catheter per applicable sections of the indicated standards and/or validated internal test methods:
Catheter – Guidance for Industry and FDA Staff - Coronary and Peripheral Arterial Diagnostic Catheters (July 15, 2003)

- Dimensions - Outer Diameter performed for subject device, other dimensions leveraged from predicate.
- Shape Master – Performed for subject device.
- Pull Test – Performed for subject device.
- Dynamic Pressure – Leveraged from predicate.
- Hydrostatic pressure – Leveraged from predicate.
- Torque Test – Performed for subject device.
- Particulates – Performed for subject device.
- Kink Radius – Performed for subject device.

Risk Analysis

A risk analysis was conducted in accordance with 14971, taking into account the modifications to the predicate device, and it was determined that no new risks were identified.

VII. CLINICAL PERFORMANCE

No clinical data was required in support of the proposed change to the predicate device cleared under K970854.

VIII. CONCLUSIONS

The INFINITI™ Ambi Angiographic Catheter was found to be substantially equivalent in its design, intended use, technology, principal of operation, and performance to the predicate device. There are no significant differences between the INFINITI™ Ambi Angiographic Catheter and the predicate device that raise new issues of safety and effectiveness.