February 26, 2021

Cordis Corporation
Crystal Placona
Manager, Regulatory Affairs
14201 NW 60th Avenue
Miami Lakes, Florida 33014

Re: K202167
Trade/Device Name: Brite Tip Radianz Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: January 26, 2021
Received: January 27, 2021

Dear Crystal Placona:

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,

Finn Donaldson
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)*
K202167

Device Name
BRITE TIP RADIANZ™ Guiding Sheath

Indications for Use *(Describe)*
BRITE TIP RADIANZ™ Guiding Sheath is indicated for intravascular introduction of interventional and/or diagnostic devices into the peripheral vasculature through the radial artery.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

I. SUBMITTER

Applicant:
Cordis Corporation
14201 North West 60th Avenue
Miami Lakes, Florida 33014 USA
Establishment Registration: 1016427

Contact:
Crystal Placona
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Tel: (786) 313-8325
crystal.placona@cardinalhealth.com

Date Prepared: July 31, 2020

II. DEVICE

Name of Device: **BRITE TIP RADIANZ™ Guiding Sheath**
Common Name: Vascular Catheter Introducer
Classification Name: Introducer, Catheter (21 CFR 870.1340), Class II
Product Code: DYB

III. PREDICATE DEVICE

Terumo R2P™ Destination Slender™ cleared on 11/21/2014 under K171491.

Predicate device cited above has not been the subject of a recall.

IV. INDICATIONS FOR USE

BRITE TIP RADIANZ™ Guiding Sheath is indicated for intravascular introduction of interventional and/or diagnostic devices into the peripheral vasculature through the radial artery.

The Indications for Use statement for BRITE TIP RADIANZ™ is similar to that of the predicate device. The subject and predicate devices have the same fundamental intended use, which is to facilitate introduction of interventional and/or diagnostic devices into the peripheral vasculature through the radial artery. Minor differences in the Indications for Use statements do not alter the intended use.

V. DEVICE DESCRIPTION

Each BRITE TIP RADIANZ™ device consists of a 6F compatible guiding sheath, a vessel dilator (0.035” guidewire compatible) and a removable hemostasis valve.

The guiding sheath has a lubricious hydrophilic coating to enhance entry and withdrawal during vessel access, and a low-profile outer diameter with a smooth transition to the vessel dilator to minimize or prevent radial vasculature trauma and spasm of the radial artery. The sheath is available in two lengths, 110 cm and 135 cm. The sheath hub is an over-molded hub with a luer and is compatible with the removable hemostasis valve provided (described

below) and with other hemostasis valves or common vascular accessories of the user's choice.

The vessel dilator is compatible with 0.035" guidewires (not included) and is tapered such that it creates a smooth transition between the guiding sheath tip and the guidewire. The vessel dilator hub is over molded and includes a locking feature located in the distal end of the hub to facilitate locking the vessel dilator to the sheath cannula proximal hemostasis valve.

The system contains a removable hemostasis valve to facilitate entry and withdrawal of intravascular devices through the guiding sheath and minimize the backflow of blood. It also has a side-port arm with attached 3-way stopcock for flushing or aspiration. The pre-assembled hub connector is removable, such that it can be exchanged for a hemostasis valve or other common vascular accessory of the user's preference.

BRITE TIP RADIANZ™ device is for professional use in a hospital, catheterization laboratory, or other suitable healthcare facility only. It is available in the following configurations:

Catalog Numbers	Description
687280110	6Fr, straight, 110 cm
687280135	6Fr, straight, 135 cm

The materials of construction of the BRITE TIP RADIANZ™ device are as follows:

Component	Description	Materials	Patient Contact
Guiding Sheath	Tubing	Pebax/Nylon compound, Vestamid, Bismuth subcarbonate, Color Conc. (various), hydrophilic coating	Direct (≤ 24hr)
	Radiopaque Tip	Nylon with Bismuth Trioxide	Direct (≤ 24hr)
	Liner	PTFE	Direct (≤ 24hr)
	Braiding	Stainless Steel	None
	Hub	Polycarbonate	Indirect (≤ 24hr)
Hemostasis Valve	Hemovalve Connector	Polycarbonate, Polyethylene, Colorant	Indirect (≤ 24hr)
	Cap, brim	Polyethylene, Colorant	Indirect (≤ 24hr)
	Gasket	Silicone Rubber Elastomer, Bismuth Oxychloride	Indirect (≤ 24hr)
	Medical Fluid	Polydimethylsiloxane Fluid	Indirect (≤ 24hr)
	Adhesive	Pimelic Ketone	None
	Collar	Polyethylene, Colorant	None
	Tubing Extension (Sideport)	Polyurethane	Indirect (≤ 24hr)
	3-way Stopcock Assembly	Polycarbonate, Polyethylene	Indirect (≤ 24hr)
Vessel Dilator	Dilator Extrusion	Nylon, Barium Sulfate, Color Concentrate, MDX Lubricant	Direct (≤ 24hr)
	Dilator Hub	Nylon, Color Concentrate	Indirect (≤ 24hr)

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

BRITE TIP RADIANZ™ and the predicate device both facilitate access into the peripheral vasculature through the radial artery using the same fundamental mechanism of action. Both contain a traditional sheath with a bleed-back valve and a stopcock. Sheaths for both devices have a hemostasis valve. BRITE TIP RADIANZ™ and R2P Destination Slender™ both have hydrophilic coatings. During radial access of both devices, the dilator taper and close fit with the sheath combined with the hydrophilic coating on the sheath act to expand the arteriotomy and facilitate entry into the radial artery. Taper length of the BRITE TIP RADIANZ™ dilator is comparable to that of the R2P Destination Slender™. Thus, both the BRITE TIP RADIANZ™ and R2P Destination Slender™ have a combination of a hydrophilic coating, tip geometry and fit with dilator to facilitate entry and reduce friction within the radial artery.

BRITE TIP RADIANZ™ has the following similarities to the predicate device:

- Same intended use
- Same principle of operation
- Same mechanism of action
- Same method of sterilization and sterility assurance level
- Same biocompatibility classification
- Biocompatible for intended use
- Labeled non-pyrogenic
- Similar materials
- Similar components
- Similar device dimensions
- Similar packaging configuration
- Similar compatibility with other devices used in radial access procedures

The following technological differences exist between the subject and predicate device:

- BRITE TIP RADIANZ™ Guiding Sheath is secured in a tray whereas the predicate device is secured by a mounting card.

Based on a thorough analysis of technological characteristics, including design, materials, dimensions, mechanism of action, and clinical use, the BRITE TIP RADIANZ™ device is substantially equivalent to the predicate device.

VII. PERFORMANCE DATA

The performance data described below were provided in support of the substantial equivalence determination.

Biocompatibility Testing

BRITE TIP RADIANZ™ Guiding Sheath, like the predicate, is an externally communicating device with limited contact duration (≤ 24 hours) with circulating blood. Biocompatibility testing was performed for BRITE TIP RADIANZ™ in accordance with FDA Guidance, Use of International Standard ISO 10993-1, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* (June 2016) and ISO 10993-1:2018, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. On the basis of the testing listed below, BRITE TIP RADIANZ™ is biocompatible for its intended use:

- Physical and/or Chemical Information

- Chemical Characterization
- Toxicology Risk Assessment
- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemocompatibility

Sterilization

Testing was performed to permit the adoption of the subject device into existing Cordis validated sterilization cycles. The sterilization cycle used to sterilize BRITE TIP RADIANZ™ Guiding Sheath was validated per ISO 11135:2014+A1:2018 *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 10993-7:2008, *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*. The levels of residuals will not exceed 4 mg EO /device or 9 mg ECH/device.

Bench Testing

The substantial equivalence of the BRITE TIP RADIANZ™ Guiding Sheath to the predicate device has been demonstrated through data collected during non-clinical design verification and validation testing. The following testing was successfully performed or leveraged for the BRITE TIP RADIANZ™ device per applicable sections of the indicated standards and/or validated internal test methods:

- Sheath – ISO 11070:2014, 10555-1:2013+A1:2017, ISO 594-1:1986, ISO 594-2:1998, USP 788 and internal test methods
- Dilator – ISO 11070:2014, 10555-1:2013+A1:2017, USP 788 and internal test methods
- Hemostasis Valve – ISO 80369-7:2016, USP 788 and internal test methods
- Packaging integrity – ISO 11607-1:2019 and ISO 11607-2:2019

The passing results for the testing provide reasonable assurance that the subject device has been designed to meet its intended use.

Clinical Studies

No clinical studies were deemed necessary to support substantial equivalence.

VIII. CONCLUSIONS

The information presented in this Premarket Notification demonstrates the following for the BRITE TIP RADIANZ™ Guiding Sheath:

- BRITE TIP RADIANZ™ has a legally-marketed predicate
- BRITE TIP RADIANZ™ has the same Intended Use as the predicate
- BRITE TIP RADIANZ™ incorporates the same fundamental technology as the predicate

- Accepted scientific methods and international standards were used to evaluate substantial equivalence of the BRITE TIP RADIANZ™ device relative to the predicate
- Performance characteristics of the BRITE TIP RADIANZ™ device are equivalent to the predicate device.

On the basis of the intended use, design, performance characteristics and non-clinical performance testing, and of detailed comparisons to the legally marketed predicate device, it is concluded that the BRITE TIP RADIANZ™ Guiding Sheath is substantially equivalent to R2P ™ Destination Slender™.