October 09, 2020

Cordis Corporation
Luis Davila
Principal Specialist, Regulatory Affairs
14201 NW 60th Ave
Miami Lakes, Florida 33014

Re: K201377
Trade/Device Name: SABERX RADIANZ Percutaneous Transluminal Angioplasty Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: September 01, 2020
Received: September 04, 2020

Dear Luis Davila:

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

Gregory O'Connell
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)*
K201377

Device Name
SABERX RADIANZ™ Percutaneous Transluminal Angioplasty Dilatation Catheter

Indications for Use *(Describe)*
The SABERX RADIANZ™ PTA Catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries. The device is also indicated for post-dilation of balloon-expandable and self-expanding stents in the 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.

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary - K201377

I. SUBMITTER

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

Contact:
Luis Gerardo Davila
Cordis Corporation, a Cardinal Health Company
5452 Betsy Ross Drive
Santa Clara, CA 95054, USA
Date Prepared: May 21, 2020

II. PROPOSED DEVICE

Name of Device: SABERX RADIANZ™ Percutaneous Transluminal Angioplasty Dilatation Catheter
Common Name: Percutaneous Transluminal Angioplasty Catheter
Classification Name: Percutaneous Catheter (21 CFR 870.1250), Class II
Product Code: LIT

III. PREDICATE DEVICE

Crosstella RX PTA Balloon Dilatation Catheter cleared on 01/22/2016 under K152873.

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

Reference Devices: SABER™ PTA Dilatation Catheter cleared on 06/27/2014 under K133843 and SABERX™ PTA Dilatation Catheter not cleared in the US Market.

IV. DEVICE DESCRIPTION

The SABERX RADIANZ™ Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter is a single-use sterile device, sterilized by ethylene oxide.

The SABERX RADIANZ™ Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter (hereafter referred to as “SABERX RADIANZ™”) is a Rapid Exchange design, consisting of a single inflation lumen and a distal guidewire lumen. The guidewire lumen permits the use of a guidewire (0.018 in.) to facilitate advancement of the catheter to and through the stenosis to be dilated. It begins at the distal tip and terminates at the guidewire exit port. The guidewire exit-port (hole) is 40 cm from the distal tip. The proximal hub section of the catheter provides a clear, one-piece hub with a single-luer port for inflation and deflation of the balloon. The coaxial, concentric dual lumen distal shaft connects proximally at the guidewire exit port and distally to the balloon. The proximal shaft with a supporting stainless-steel core wire connects proximally to the hub and distally to the guidewire exit port. The balloon is designed to provide an inflatable segment of

known diameter and length at recommended pressures. A balloon protector is placed over the balloon to maintain a low profile. The catheter includes a tapered tip to facilitate advancement of the catheter to and through the stenosis. A lubricious hydrophilic coating covers the distal tip, balloon, and a portion of the shaft, to facilitate balloon placement. The SABERX RADIANZ™ catheter will have multiple radiopaque marker bands that provide fluoroscopic visual reference points to facilitate balloon positioning within the vessel.

The SABERX RADIANZ™ catheter is compatible with standard 0.018" guidewires and 4F, 5F, or 6F catheter sheath introducers. The usable catheter length is 190 cm and the proximal shaft has two exit markers located at 115 cm and 140 cm from the distal tip.

The SABERX RADIANZ™ catheter is available in eighty-two (82) product configurations with balloon diameters of 2.00 - 8.00 mm in 0.50 mm or 1.00 mm increments. The working lengths of the treatment balloon will be offered in lengths from 20 mm to 300 mm.

The associated accessories for SABERX RADIANZ™ include:

- Flushing Needle.

The SABERX RADIANZ™ is for use in a catherization lab, hospital or other suitable healthcare facility by appropriately trained medical professionals only.

V. INDICATIONS FOR USE

The SABERX RADIANZ™ PTA Catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries. The device is also indicated for post-dilation of balloon-expandable and self-expanding stents in the peripheral vasculature

The Indications for Use statement for SABERX RADIANZ™ is similar to the predicate device. The subject and predicate devices have the same fundamental intended use, which is to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for stent post-dilation. Minor differences in the Indications for Use statements do not alter the intended use, or raise different questions of safety and effectiveness relative to the predicate.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE AND REFERENCE DEVICES

The SABERX RADIANZ™ and the predicate device facilitate the dilation of stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the stent post-dilation in the peripheral vasculature using the same fundamental mechanism of action. Both devices, the SABERX RADIANZ™ and the predicate, have a guidewire lumen, that after gaining access, permits the use of a guidewire to facilitate advancement of the catheter to and through the stenosis to be dilated and/or to the stent to be post-dilated. Both devices have a tapered tip to facilitate advancement of the catheter to and through the stenosis to be dilated and/or to the stent for post-dilation. Both devices include a hydrophilic coating, which is applied from the distal tip and over the balloon and a portion of the distal shaft for increased lubricity. Both devices, the SABERX RADIANZ™ and the predicate device include a needle for flushing the catheter. The SABERX 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 (i.e. Catheter Sheath and Guiding Catheter).

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

- SABERX RADIANZ™ PTA Catheter is shorter; however, the working length is similar.
- SABERX RADIANZ™ PTA Catheter is secured in a tray whereas the predicate device is secured by clips.

Furthermore, the SABERX RADIANZ™ PTA Catheter (subject device) shares significant similarities with the Cordis SABER™ and SABERX™ devices. The most significant similarities are: 1) The SABERX RADIANZ™ PTA Catheter intended use is the same as the SABER™ and SABERX™ intended use and 2) the device component material compositions and the composition of the packaging materials for the SABERX RADIANZ™ PTA are the same as those of the SABER™ and/or SABERX™ catheters.

The SABERX RADIANZ™ has the following similarities to the reference devices:

- All three systems have the same intended used
- All three systems include radiopaque markers and have multiple marker bands for balloon positioning.
- All three systems have a hydrophilic coating designed to increase lubricity.
- The SABERX RADIANZ™ and SABERX™ PTA systems utilize a stainless-steel core wire.
- All three systems are compatible for 4F, 5F and 6F guiding catheter or catheter sheath introducers.
- All three systems are compatible with an 0.018” guidewire.
- All three systems utilize same device and packaging material compositions.

Based on a thorough analysis of technological characteristics, including design, materials, dimensions, mechanism of action, and clinical use, the differences between the SABERX RADIANZ™, the predicate and reference devices do not raise different questions of safety and effectiveness for intended use. No different questions of safety and effectiveness are raised by the SABERX RADIANZ™ PTA Dilatation Catheter, for which the intended use is to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries. The device is also indicated for post-dilation of balloon-expandable and self-expanding stents in the peripheral vasculature.

VII. PERFORMANCE DATA

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

Biocompatibility Testing

The SABERX RADIANZ™, like the predicate, is an externally communicating device with limited contact duration (≤ 24 hours) with circulating blood. Biocompatibility testing was performed for SABERX RADIANZ™ in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA and ISO 10993-1:2009/Cor 1:2010, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.. Based on the testing results, SABERX RADIANZ™ is biocompatible for its intended use.

Biocompatibility testing performed to the subject device is listed below

- Cytotoxicity – MEM Elution
- Sensitization – Guinea Pig Maximization
- Intracutaneous Irritation Reactivity
- Acute Systemic Toxicity
- Materials Mediated Rabbit Pyrogen
- Hemolysis – Extract / Direct Contact
- Partial Thromboplastin Time (PTT)
- Platelet & Leukocyte Counts
- Complement Activation Assay
- Bacterial Mutagenicity – Ames Assay
- In Vitro Mouse Lymphoma
- In Vivo Mouse Micronucleus
- In Vivo Thrombogenicity
- USP Physicochemical Aqueous Extract Test
- Chemical Characterization

Sterilization

The SABERX RADIANZ™ is sterilized using Ethylene Oxide. The sterilization cycle used to sterilize SABERX RADIANZ™, was validated per ISO 11135:2014+A1:2019 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/Cor:2009, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.

Bench Testing

Data collected during non-clinical design verification and validation testing demonstrate substantial equivalence of the SABERX RADIANZ™ PTA Dilatation Catheter to the predicate device. The following testing was successfully completed for the SABERX RADIANZ™ per applicable sections of the indicated standards and/or validated internal test methods:

- Catheter – FDA PTCA Guidance, USP-788 and internal test methods
    - Dimensional verification
    - Balloon Preparation.
    - Balloon Rated Burst Pressure (with and without stent)
    - Balloon Fatigue (Repeat Balloon Inflations with and without stent)
    - Balloon Compliance
    - Balloon Inflation Time
    - Balloon Deflation Time
    - Catheter Bond Strength
    - Flexibility and Kink Test
    - Torque Strength
    - Particulate Evaluation / Coating Uniformity-Integrity
- Packaging integrity – ISO 11607-1:2019 and ISO 11607-2:2019
    - Visual inspection
    - Component position
    - Peel strength
    - Bubble test
    - Particulate

The passing results for the above tests provide reasonable assurance that the subject device has been designed to meet its intended use. No different issues of safety and effectiveness relative to the predicate were raised by this testing.

Electrical safety and electromagnetic compatibility (EMC)

This section is not applicable. The SABERX RADIANZ™ PTA Dilatation Catheter contains no electronic components, and thus, no electrical safety evaluation is required.

Software Verification and Validation Testing

This section is not applicable. The SABERX RADIANZ™ PTA Dilatation Catheter contains no software, and thus, no information regarding software/firmware is required for this device.

Animal Study

No animal testing was performed for the SABERX RADIANZ™PTA Dilatation Catheter.

Clinical Studies

No clinical studies were deemed necessary to support substantial equivalence. Appropriate verification and validation of the device requirements were achieved based on the similarities of the subject device to the predicate and from the results bench testing.

VIII. CONCLUSIONS

The information presented in this Premarket Notification demonstrates the following for the SABERX RADIANZ™:

- SABERX RADIANZ™ PTA Dilatation Catheter has a legally marketed predicate.
- SABERX RADIANZ™ PTA Dilatation Catheter has the same Intended Use as the predicate.
- SABERX RADIANZ™ PTA Dilatation Catheter has the same principle of operation and mechanism of action.
- SABERX RADIANZ™ PTA Dilatation Catheter incorporates the same fundamental technology as the predicate.
- Accepted scientific methods and international standards were used to evaluate safety and performance of the SABERX RADIANZ™ PTA Dilatation Catheter relative to the predicate.
- Safety and performance characteristics of the SABERX RADIANZ™ PTA Dilatation Catheter are equivalent to the predicate device and do not raise different questions of safety and effectiveness.

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 SABERX RADIANZ™ PTA Dilatation Catheter is appropriate for its intended use and is substantially equivalent to Crosstella RX PTA Dilatation Catheter.