August 22, 2022

Cordis US Corp.
Gina Flores
Principal Specialist, Regulatory Affairs
5452 Betsy Ross Drive
Santa Clara, California 95054

Re: K221832
Trade/Device Name: SABER™ .014 PTA Dilatation Catheter; SABERX™ .014 PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: June 22, 2022
Received: June 23, 2022

Dear Gina Flores:

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,

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)*
K221832

Device Name

SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters

Indications for Use *(Describe)*

The SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters are intended to dilate stenoses in the peripheral vasculature, including femoral, popliteal and infra popliteal arteries. The device is also indicated for postdilation 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.

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510(k) Summary for K221832

I. SUBMITTER

Applicant:
Cordis US Corp
14201 North West 60th Avenue
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Establishment Registration: 1016427

Contact:
Luis Davila
Cordis US Corp
5452 Betsy Ross Drive
Santa Clara, CA 95054, USA.
Date Prepared: August 15, 2022

II. DEVICE

Name of Device: SABER™ .014 and SABERX™ .014 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 DEVICES

SLEEK® OTW PTA Balloon Dilatation Catheter cleared on 12/01/2010 under K102035 and SLEEK® PTA Balloon Dilatation Catheter cleared on 02/08/2008 under K072947.

Additional Reference Devices

NANOCROSS™ ELITE OTW PTA Dilatation Catheter .014 cleared on 7/18/201 under K141118

RAPIDCROSS™ PTA Balloon Dilatation Catheter RX .014 cleared on 5/24/2013 under K130911

ULTRAVERSE® RX PTA Dilatation Catheter cleared on 5/30/2013 under K131199

Predicate/reference devices cited above have not been the subject of a recall.

IV. DEVICE DESCRIPTION

The SABER™ .014 and SABERX™ .014 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter are single-use sterile devices, sterilized by ethylene oxide.

The **SABER™ .014 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter** is an over-the-wire (OTW) coaxial lumen catheter with a semi-compliant balloon mounted on its distal end. It is compatible with 0.014" (0.3556 mm) guidewire. The catheter is available in working

lengths of 90 cm and 150 cm with balloon diameters ranging from 1.25 mm to 5.0 mm, and balloon lengths ranging from 15 mm to 300 mm.

Radiopaque marker bands indicate the dilating section of the balloon and aid in balloon placement. For balloon lengths greater than or equal to 100 mm, the distal section will have two (2) adjacent marker bands and the proximal section will have one (1) marker band. For balloon lengths less than 100 mm, the distal and proximal section will each have one (1) marker band. The catheter tip is tapered to ease entry into peripheral arteries and to facilitate the crossing of tight stenoses. SABER™ .014 balloons are coated with a dual-layer hydrophilic material designed to increase lubricity throughout the lifetime of the device.

The working pressure range for the balloon is between the nominal pressure and the rated burst pressure. All balloons distend to sizes above the nominal size at pressures greater than the nominal pressure. Consult the compliance chart on the tray label for typical diameters of the balloons at given pressures.

The balloon lumen is used to inflate and deflate the balloon. The nominal balloon size in printed on the hub. The guidewire lumen is used to track the catheter over a prepositioned guidewire.

The radiopaque marker bands (the length between the outer edge of most proximal to the outer edge of most distal marker band) indicate the stated nominal length of the balloon.

The **SABERX™ .014 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter** is a catheter with a distal inflatable balloon. The catheter is available in working lengths of 90 cm, 150 cm and 200 cm with balloon diameters ranging from 1.25 mm to 6.0 mm, and balloon lengths ranging from 15 mm to 300 mm. The catheter utilizes a Rapid Exchange design, consisting of a single inflation lumen and a distal guidewire lumen. The guidewire lumen begins at the distal tip and terminates at the guidewire exit port. The proximal hub is used as a balloon inflation port.

Radiopaque marker bands indicate the dilating section of the balloon and aid in balloon placement. For balloon lengths greater than or equal to 100 mm, the distal section will have two (2) adjacent marker bands and the proximal section will have one (1) marker band. For balloon lengths less than 100 mm, the distal and proximal section will each have one (1) marker band. The catheter tip is tapered to ease entry into peripheral arteries and to facilitate the crossing of tight stenoses. SABERX™ .014 balloons are coated with a dual-layer hydrophilic material designed to increase lubricity throughout the lifetime of the device.

The working pressure range for the balloon is between the nominal pressure and the rated burst pressure. All balloons distend to sizes above the nominal size at pressures greater than the nominal pressure. Consult the compliance chart on the tray label for typical diameters of the balloons at given pressures.

The radiopaque marker bands (the length between the outer edge of most proximal to the outer edge of most distal marker band) indicate the stated nominal length of the balloon.

The associated accessories for SABERX™ .014 PTA Dilatation Catheter include:

- Flushing Needle

The SABER™ .014 and SABERX™ .014 PTA Dilatation Catheter are for use in a catherization lab, hospital or other suitable healthcare facility by appropriately trained medical professionals only.

V. INDICATIONS FOR USE

The SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters are intended to dilate stenoses in the peripheral vasculature, including femoral, popliteal and infra-popliteal 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 SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters is similar to the predicate devices. The subject and predicate devices have the same fundamental intended use, which is to dilate stenoses in femoral, popliteal, infra popliteal. Minor differences in the Indications for Use statements do not affect the safety and effectiveness of the device relative to the predicate.

As the predicate devices, The SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters are not to be used in the coronary arteries.

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

The SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters and the predicate devices facilitate the dilation of stenoses in femoral, popliteal and infra-popliteal in the peripheral vasculature using the same fundamental mechanism of action. The SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters have the additional indication for stent post dilation, as do the reference devices RapidCross™ 0.14 RX PTA and NanoCross™ Elite 0.14 RX PTA.

The SABER™ .014, SABERX™ .014 PTA Dilatation Catheters and the predicate devices 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. The subject and predicate devices have a tapered tip to facilitate advancement of the catheter to and through the stenosis to be dilated. The subject and predicate devices include a lubricious coating, which is applied from the distal tip and over the balloon and a portion of the distal shaft for increased lubricity.

The SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters have the following similarities to the predicate and reference devices:

- 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., Guidewire, Catheter Sheath and Guiding Catheter).

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

- SABER™ .014 and SABERX™ PTA Dilatation Catheters have the guidewire lumen silicone coated.
- SABERX™ .014 PTA Dilatation Catheter is provided with a flushing needle while the predicate devices do not include a flushing needle.
- The SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters have the additional indication for stent post dilation.

Based on a thorough analysis of technological characteristics, including design, materials, dimensions, mechanism of action and clinical use, the differences between the SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters and the predicate devices do not raise any additional questions of safety and effectiveness. No new questions of safety and effectiveness are raised by the SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters for their intended use.

VII. PERFORMANCE DATA

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

Biocompatibility Testing

The SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters, as the predicates, are externally communicating devices with limited contact duration (≤ 24 hours) with circulating blood. Biocompatibility testing was performed for SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters 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, SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters are biocompatible for their intended use.

Biocompatibility testing performed to the subject device is listed below:

- MEM Elution Using L-929 Mouse Fibroblast Cells
- Hemolysis Assay - Direct Contact and Extract Method
- Complement Activation SC5b-9 Assay with Sponsor-Supplied Comparison Article
- In Vitro Mouse Lymphoma with Extended Treatment
- Bacterial Mutagenicity Test - Ames Assay
- Guinea Pig Maximization Sensitization Test
- Acute Systemic Injection Test
- Intracutaneous Irritation Test
- Materials Mediated Rabbit Pyrogen
- Thromboresistance Evaluation

Sterilization

The SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters are sterilized using Ethylene Oxide. The sterilization cycle used to sterilize SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters, was validated per 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.*

Bench Testing

The safety and effectiveness of the SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters and their substantial equivalence to the predicate devices, has been demonstrated through data collected during non-clinical design verification and validation tests and analyses. The following testing was successfully completed for the SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters 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 Deflation Time
    - Catheter Bond Strength
    - Flexibility and Kink Test
    - Torque Strength
    - Particulate Evaluation / Coating Uniformity-Integrity
    - Radiopacity

- 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 SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters contain no electronic components, and thus, no electrical safety evaluation is required.

Software Verification and Validation Testing

This section is not applicable. The SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters contain no software, and thus, no information regarding software/firmware is required for this device.

Animal Study

The safety and effectiveness of the SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters have been demonstrated through data collected during Design Validation (Animal Study) tests and analyses. The following testing was successfully completed for the SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters per applicable sections of the indicated standards and/or validated internal test methods.

- Insertion and withdrawal force
- Kinking
- Pushability
- Crossability
- Atraumatic Tip
- Guidewire compatibility
- Fluoroscopy
- Balloon visibility
- Radiopacity
- Balloon inflation and deflation
- Luer lock compatibility
- Aseptic presentation and product removal
- Torque and kink resistance

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 SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters

- SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters have a legally marketed predicate
- SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters have the same Intended Use as the predicate
- SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters have the same principle of operation and mechanism of action
- SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters incorporate the same fundamental technology as the predicate

- Accepted scientific methods and international standards were used to evaluate safety and effectiveness of the SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters relative to the predicate
- Safety and performance characteristics of the SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters are equivalent to the predicate devices and do not raise any additional 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 devices, it is concluded that the SABER™ .014 and SABERX™ .014 PTA Dilatation Catheters are appropriate for their intended use and are substantially equivalent to SLEEK® OTW and SLEEK® PTA Dilatation Catheters.