April 23, 2021

Cordis Corporation
Wai Morgan
Regulatory Affairs Principal Specialist
14201 N.W. 60th Avenue
Miami Lakes, Florida 33014

Re: K210626
Trade/Device Name: SABER .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: February 26, 2021
Received: March 2, 2021

Dear Wai Morgan:

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)*
K210626

Device Name
SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter

Indications for Use *(Describe)*
SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is also indicated for post-dilatation 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 SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter

I. Applicant/Manufacturer Information

Company: Cordis Corporation
Type of 510(k) Submission: Traditional 510(k) Premarket Notification
510(k) Correspondent: Ms. Wai Morgan(wai.morgan@cardinalhealth.com)
Submission date: February 26, 2021

II. Regulatory Information

Proposed Device:

- Trade/Proprietary Name: SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter
- Regulation Name: Percutaneous Catheter
- Classification Panel: Cardiovascular
- Device Class: II
- Regulation Number: 21 CFR 870.1250
- Product Code: LIT
- 510k Submitter: Cordis Corporation, (a Cardinal Health Company)
  14201 N.W. 60th AVE. Miami Lakes, FL 33014
  Tel: 305-528-6181
  Establishment registration number: 1016427

- **Indications for Use**: The SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is also indicated for post-dilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.

Predicate Device:

- Trade/Proprietary Name: SABER™.035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter
- Regulation Name: Percutaneous Catheter
- Product Code: LIT
- 510k number: K201333
- 510k Submitter: Cordis Corporation, (a Cardinal Health Company)
  14201 N.W. 60th AVE. Miami Lakes, FL33014

- **Indications for Use**: SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and

for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

III. Device Description of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter:

The SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter is a catheter with a distal inflatable balloon, which is the same device as its predicate, SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter (K201333), with an additional indication. The device has identical technological characteristics as the predicate, SABER™ .035 PTA Dilatation Catheter (K201333). SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter is designed for use with a 0.035" guide wire and a catheter sheath introducer and is available in a variety of diameters and lengths. The radiopaque marker bands indicate the dilating section of the balloon and aid in balloon placement. The catheter tip is tapered to ease entry into peripheral arteries and to facilitate crossing of tight stenoses. SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter is compatible with standard .035" guide wires and 5Fr, 6Fr and 7Fr catheter sheath introducers (CSI).

The SABER™ .035" PTA Dilatation Catheter has identical device/component constructions as the predicate, SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter (K201333). Same as the predicate, the balloon of the SABER™ .035 PTA Dilatation Catheter has radiopaque markers at the distal and proximal ends of the balloon working length to aid in balloon placement when under fluoroscopy. The SABER™ .035 PTA Dilatation Catheter has a proximal hub assembly that contains a luer locking connector with a balloon inflation port and a guide wire port. The balloon is inflated by injecting diluted contrast medium through the inflation port of the hub and the inflation lumen connected to the balloon.

The SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter is intended for single use only and is provided sterile.

IV. Substantial Equivalence Assessments of Technological Characteristics:

Fundamental technological characteristics and raw material construction of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter are identical to the predicate device, SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter (K201333). . The operation principle, clinical applications, and instructions for use of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter are similar to the predicate device. Both the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter and the predicate device (K201333) are indicated for use to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures. In addition, the subject SABER™.035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter is also indicated for post-dilatation of balloon-expandable and self-expanding stents in

the peripheral vasculature. Both the proposed and predicate devices are provided sterile with ethylene oxide sterilization and intended for single use only.

The proposed and predicate devices share the identical patient contacting materials, and the biocompatibility testing of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter which was performed to verify conformance to the same requirements of the ISO 10993-1 (2018) standard for biological safety evaluation. Given all the critical technological characteristics as well as indications for use/intended use are similar, the proposed SABER™ .035 PTA Dilatation Catheter is assessed as substantially equivalent to the predicate device, SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter (K201333).

V. Biocompatibility Assessment

In accordance with ISO 10993-1: 2018, Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process, the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter is classified as "Externally Communicating Devices, Circulating
blood, Limited Contact (<24 hrs). This is the same classification of the biocompatibility evaluation as the predicate, SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter (K201333).

The biocompatibility testing of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter listed below has been conducted at a US testing laboratory, in order to ensure that FDA's latest
consensus standards with respect to biological safety evaluations are met for the proposed device. The favorable biocompatibility test results provide assurance of the biologically safety profile of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter.

GLP Biocompatibility Testing Performed:

- Extractables of SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter
- Cytotoxicity-ISO MEM Elution Using L-929 Mouse Fibroblast Cell
- ISO Guinea Pig Maximization Sensitization
- ISO Intracutaneous Irritation
- ISO Acute Systemic Toxicity
- ISO Materials Mediated Rabbit Pyrogen
- Hemocompatibility-ASTM Hemolysis
- Hemocompatibility-Complement Activation
- Hemocompatibility Thromboresistance Evaluation
- Chemical Characterization
- Toxicology Risk Assessment Report

VI. Design Verification and Validation Testing

Design Verification and Validation (DV&V) testing was performed to verify that the proposed SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter meets the pre-determined safety and performance requirements. Testing was also conducted to verify the effectiveness of the implemented risk control measures to mitigate the risks identified within the risk management process per ISO 14971: Medical Devices-Application of Risk Management to Medical Devices. The following design verification or performance testing of SABER™ .035 PTA Dilatation Catheter have been completed with favorable test results, meeting the applicable ISO standards and FDA's recognized consensus standards pertaining to evaluations of PTA Catheters.

Design Verification Performance Testing:
T=0 Baseline Sample Testing and T=3 Years Accelerated Aging Testing of Finished Devices of SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter:

- CSI Withdrawal
- Guide Wire Compatibility
- Usable catheter length
- Kink diameter
- Visual coating integrity
- Particulate Count Testing
- Outer surface lubricity
- Marker Band Locations
- Inflation / Deflation
- No Leakage
- Connector compatibility
- Hub-Catheter tensile test
- Balloon proximal tensile test
- Balloon Distal Tip tensile test
- Catheter Body Burst (Inflation Lumen)
- Catheter Body Burst (Guide Wire Lumen)
- Torque-ability
- Balloon Working Length
- Balloon Diameter
- Balloon compliance
- Balloon Burst
- System Fatigue

VII. Sterilization, Microbiology and Packaging Validation and Verification

The EO sterilization process for the SABER .035 PTA Dilatation Catheter and the predicate, SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter (K201333) fall under the same sterilization product family category set up by

Confluent Medical Technologies, which is the physical manufacturer of both the SABER .035 PTA Dilatation Catheter and the predicate, SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter (K201333).

The product family under which both the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter and the predicate under K201333 have been previously validated using the overkill approach for EO sterilization. The predicate and proposed device share identical technological characteristics, which have been considered and assessed in reaching the decision to have the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter be included into the validated sterilization process used at the Confluent Medical Technologies facility.

The favorable results of the sterilization adoption assessments demonstrate it is appropriate to include and adopt the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter into the EO processing product family using sterilization cycle 2.0 at Synergy Health. For a complete listing of the sterilization adoption report and sterilization validation report (cycle 2.0- Synergy Health), please refer to **Section 18.1**, Ethylene Oxide Sterilization Validation of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter in **eCopy 002.**

- Sterilization Adoption Validation of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter
- 2020 Sterilization Validation Report for Cycle 2 at Steris AST

The microbiology validation and verification evaluations were completed for the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter with the bioburden and bacterial endotoxin test (BET) results:

- Microbiology Validation Report
- Bioburden Test Method Validation
- Endotoxin LAL Test Before Sterilization
- Endotoxin LAL Test After Sterilization
- Bioburden Test During PQ

The packaging design validation and verification testing of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter has been completed with both T=0 baseline samples and T=3 Year, accelerated aging samples of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter:

- T0 Sample: Packaging Validation and Verification
- T3 Year Sample: Packaging Validation and Verification

VIII. Substantial Equivalence Assessment

From the standpoint of safety and performance evaluation, the proposed SABER™ .035 PTA Dilatation Catheter demonstrated conformance to the FDA's recognized standards. The favorable test results of the proposed device which confirmed to meet the FDA's recognized standards as well as the manufacturer's design verification requirements further demonstrated an equivalent profile of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter in safety and essential performance as the predicate device, SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter (K201333).

The proposed SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter is assessed substantially equivalent to the predicate device given the fact that its indications for use/intended use, fundamental technological characteristics are identical to the predicate device, SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter (K201333). The favorable results of the aforementioned safety and performance testing demonstrate conformance to the FDA's recognized standards and further demonstrate that no different questions in safety and effectiveness assessment are being raised compared to the predicate device.