September 11, 2020

Cordis Corporation
Kyungyoon Kang
Regulatory Affairs Manager
14201 N.W. 60th Ave.
Miami Lakes, Florida 33014

Re: K201333
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: July 28, 2020
Received: July 31, 2020

Dear Kyungyoon Kang:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201333

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

Indications for Use *(Describe)*
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.

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: 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: Mr. Kyungyoon Kang
(Kyungyoon.kang@cardinalhealth.com)
Submission date: May 8th, 2020

II. Regulatory Information-Assigned 510(k) Number: K201333

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, FL33014
  Tel: 408-273-3121
  Fax: 408-955-0704
  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.

Predicate Device:

- Trade/Proprietary Name: Powerflex™ Pro Percutaneous Transluminal Angioplasty Catheter
- Regulation Name: Percutaneous Catheter
- Product Code: LIT
- 510k number: K121442
- 510k Submitter: Cordis Corporation, (a Johnson & Johnson Company)
  430 Route 22 East, Bridgewater, NJ 08807
- **Indications for Use**: The Powerflex™ Pro Percutaneous Transluminal Angioplasty 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.

III. Device Descriptions 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 shares the similar technological characteristics as the predicate, Powerflex Pro PTA Catheter. The 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. The 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" Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter has similar device/component constructions as the predicate, Powerflex Pro PTA Catheter. Same as the predicate, the balloon of the SABER™ .035 Percutaneous Transluminal Angioplasty (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 Percutaneous Transluminal Angioplasty (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 of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter are similar to the predicate device, Powerflex™ Pro Percutaneous Transluminal Angioplasty Catheter. The overall raw material construction of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter is similar to the predicate device. 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, as both devices are used 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. 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 similar patient contacting materials, and the biocompatibility testing of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter was performed to verify conformance to the same requirements of the ISO 10993-1 (2018) standard for biocompatibility evaluation. Given all the critical technological characteristics as well as indications for use/intended use are similar, the proposed SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter is assessed as substantially equivalent to the predicate device, Powerflex Pro PTA Catheter.

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, Powerflex Pro PTA Catheter (K152740).

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 biocompatibility evaluations are met for the proposed device. The favorable biocompatibility test results provide assurance of the biologically safe profile of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter.

GLP Biocompatibility Testing Performed:

- Extractables of SABER™ .035 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 were performed to verify that the proposed SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter meets the pre-determined design verification and validation 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 Percutaneous Transluminal Angioplasty (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 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter and the predicate, Powerflex Pro PTA Catheter (K121442) fall under the same sterilization product family category set up by Confluent Medical Technologies, which is the physical manufacturer of both the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter and the predicate, Powerflex Pro PTA Catheter.

The product family under which both the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter and the predicate, Powerflex Pro PTA Catheter

(K121442) fall, has been previously validated using the overkill approach for EO sterilization. The predicate, Powerflex Pro PTA Catheter and the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter share highly similar technological characteristics, which have been considered 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 the validated sterilization cycle.

- Sterilization Adoption Validation of the SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter
- Sterilization Validation Report

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 have 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

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 are identical, and its fundamental technological characteristics are similar to the predicate device, Powerflex Pro PTA Catheter.

The proposed SABER™ .035 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter demonstrate conformance to the FDA’s recognized standards. The favorable test results of the proposed device have further demonstrated to fulfill the design

verification requirements and support the substantially equivalent profile of the SABER™ .035 Percutaneous Transluminal Angioplsty (PTA) Dilatation Catheter to the predicate device, Powerflex Pro PTA Catheter. The favorable results of the design verification and validation testing show that no new questions of safety or effectiveness are raised compared to the predicate device.