April 18, 2018

Cordis Corporation
Ms. Ankita Phophalia
Project Manager, Regulatory Affairs
1820 McCarthy Boulevard
Milpitas, California 95035

Re: K180081
Trade/Device Name: RAILWAY Sheathless Access System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 16, 2018
Received: March 19, 2018

Dear Ms. Phophalia:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K180081

Device Name
RAILWAY Sheathless Access System

Indications for Use *(Describe)*
The RAILWAY Sheathless Access System is indicated for use in radial arterial procedures requiring percutaneous introduction of intravascular devices.

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.

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510(k) Summary – K180081

I. SUBMITTER

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

Contact:
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Milpitas, CA 95035 USA
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Fax: (408) 955-0704

Date Prepared: January 10, 2018

II. DEVICE

Name of Device: **RAILWAY™ Sheathless Access System**
Common Name: Vascular Catheter Introducer
Classification Name: Introducer, Catheter (21 CFR 870.1340), Class II
Product Code: DYB

III. PREDICATE DEVICE

Terumo Glidesheath Slender® cleared on 11/21/2014 under K142183

Reference device
Terumo Glidesheath Slender® cleared on 12/11/2012 under K122980
Asahi Sheathless Eaucath Coronary Guide Catheter cleared on 10/24/2013 under K132556

None of the predicate or reference devices cited above have been the subject of a recall.

IV. DEVICE DESCRIPTION

The RAILWAY™ Sheathless Access System is indicated for use in radial arterial procedures requiring percutaneous introduction of intravascular devices.

The RAILWAY™ Sheathless Access System (hereafter referred to as “RAILWAY System” or “RAILWAY”) facilitates the direct radial access of separately sold Cordis guiding catheters. Each RAILWAY System consists of two 136 cm nylon vessel dilators (0.021” and 0.035” guidewire compatible), a 20 Gauge IV cannula needle and/or a 21 Gauge stainless steel access needle, and a 45 cm 0.021” mini-guidewire (either stainless steel or hydrophilic coated Nitinol). The system configurations containing the hydrophilic guidewire do not contain a bare needle. The RAILWAY

System has been dimensionally optimized for use with Cordis guiding catheters. The compatible guiding catheters and 0.035” guidewire are not included in the system.

The RAILWAY dilators have a tapered tip and a lubricious hydrophilic coating on the distal 20 cm section to facilitate access and ease of insertion. The geometry of the RAILWAY dilator taper and outer diameter (OD) have been optimized to provide atraumatic transitions between the dilator and a guiding catheter and between the dilator and guidewire. The dilator compatible with a 0.021” guidewire is intended for use in combination with a compatible guiding catheter to initiate sheathless (i.e. without a catheter sheath introducer) radial vascular access via insertion over a guidewire into the skin, subcutaneous tissue, and artery. After access is achieved, using either RAILWAY or a traditional catheter sheath introducer, the 0.035” RAILWAY dilator can be used to support the tracking of a compatible guiding catheter over a guidewire up to but not beyond the subclavian artery.

RAILWAY is available in ten (10) product configurations which differ on the basis of guiding catheter compatibility (catheter brand and French size) and the specific wire and needle(s) included in the system, as indicated in the table below. The dilators are color coded by size to align with accepted conventions for the guiding catheters to which the dilators are compatible. The RAILWAY System is a single-use sterile device, sterilized by ethylene oxide.

The RAILWAY System is compatible with 5F, 6F and 7F guiding catheters of 90 cm and 100 cm lengths. The dilators have been optimized for fit with either the Cordis VISTA BRITE TIP® or Cordis ADROIT® guiding catheters and have not been dimensionally optimized for compatibility with other guiding catheters. The appropriate RAILWAY dilator must be chosen to match the guidewire and guiding catheter sizes selected for the procedure. The RAILWAY System is for professional use in a hospital, catheterization laboratory, or other suitable healthcare facility only.

RAILWAY™ Sheathless Access System Product Configurations

Catalog Code	Access Mini-GuideWire	Access Needle	Vessel Dilator Color	Recommended Guiding Catheter Compatibility (Inner Diameter)	Dilator Guidewire Compatibility	Dilator Max Outer Diameter
RW5ADTH	Hydrophilic	IV	Gray	5F Cordis ADROIT® (0.058”)	0.021" and 0.035"	0.057” / 1.45 mm
RW5ADTB	Bare	Bare/IV				
RW5VBTH	Hydrophilic	IV		5F Cordis VISTA BRITE TIP® (0.056”)	0.021" and 0.035"	0.056” / 1.41 mm
RW5VBTB	Bare	Bare/IV				
RW6ADTH	Hydrophilic	IV	Green	6F Cordis ADROIT® (0.072”)	0.021" and 0.035"	0.071” / 1.80 mm
RW6ADTB	Bare	Bare/IV				
RW6VBTH	Hydrophilic	IV		6F Cordis VISTA BRITE TIP® (0.070”)	0.021" and 0.035"	0.070” / 1.77 mm
RW6VBTB	Bare	Bare/IV				
RW7VBTH	Hydrophilic	IV	Orange	7F Cordis VISTA BRITE TIP® (0.078”)	0.021" and 0.035"	0.078” / 1.97 mm
RW7VBTB	Bare	Bare/IV				

The materials of construction of the RAILWAY System components are as follows:

RAILWAY™ Sheathless Access System Materials of Construction		
Component	**Materials**	**Patient Contact**
Dilator	Nylon, barium sulfate, color concentrate in polymer base, black ink, hydrophilic coating	Direct (≤ 24hr)
Bare Wire	Stainless steel	Direct (≤ 24hr)
Hydrophilic Wire	Nitinol, tungsten, hydrophilic coating	Direct (≤ 24hr)
Bare Needle/ Sheath	Stainless steel, resin, polyethylene	Direct (≤ 24hr)
IV Cannula Needle	Stainless steel, MABS, polypropylene, FEP	Direct (≤ 24hr)

V. INDICATIONS FOR USE

The RAILWAY™ Sheathless Access System is indicated for use in radial arterial procedures requiring percutaneous introduction of intravascular devices.

The Indications for Use statement for RAILWAY is not identical to that of the predicate device. However, the subject and predicate devices have the same fundamental intended use, which is to facilitate placement of intravascular catheters into the radial artery. Differences in the Indications for Use statements do not alter the intended use nor do they affect the substantial equivalence of the device relative to the predicate.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The RAILWAY™ Sheathless Access System and the predicate device facilitate low profile access into the radial artery using the same fundamental mechanism of action. After gaining access with a needle and wire, the thermoplastic dilator component of each system supports the device in which it is inserted, dilates the radial artery, and provides smooth transitions between the guidewire and the device being introduced. Both devices use a tapered, dimensionally-optimized dilator supporting an outer device and a lubricious hydrophilic coating to facilitate atraumatic entry into the radial artery.

The RAILWAY System 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 devices:

- RAILWAY System does not include a sheath
- RAILWAY dilators do not include a hub
- RAILWAY dilators possess a wire port and printed markers
- RAILWAY dilator is longer; working length is similar
- Hydrophilic coating is applied to RAILWAY dilator, whereas the predicate has a hydrophilic coating on the sheath
- RAILWAY dilators can support guiding catheter tracking up to but not beyond the subclavian artery

Based on a thorough analysis of technological characteristics, including design, materials, dimensions, mechanism of action, and clinical use, the differences between the RAILWAY System and the predicate do not raise different questions of safety and effectiveness for use during radial access. No different questions of safety and effectiveness are raised by the RAILWAY System for supported tracking of a guiding catheter over a guidewire relative to use of a guiding catheter introduced through a sheath and tracked over a guidewire up to but not beyond the subclavian artery.

VII. PERFORMANCE DATA

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

Biocompatibility Testing

The RAILWAY System, like the predicate, is an externally communicating device with limited contact duration (≤ 24 hours) with circulating blood. Biocompatibility testing was performed for RAILWAY 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 16, 2016) and ISO 10993-1:2009/Cor 1:2010, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. On the basis of the testing listed below, RAILWAY is biocompatible for its intended use:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Pyrogenicity
- Genotoxicity
- Hemocompatibility

Sterilization

The sterilization cycle used to sterilize RAILWAY™ 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 10993-7:2008//Cor:2009, *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 RAILWAY™ Sheathless Access System 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 RAILWAY System per applicable sections of the indicated standards and/or validated internal test methods:

- Dilators – ISO 11070:2014, FDA PTCA Guidance, USP 788
    - Dimensional verification
    - Visual inspection
    - Dilator and guiding catheter insertion force
    - Hydrophilic coating integrity
    - Outer surface friction
    - Flushability
    - Force at break
- IV Cannula Needle – ISO 10555-1:2013 and ISO 10555-5:2013
    - Dimensional verification
    - Visual inspection
    - Strength of union of needle tube and needle hub
    - Function
    - Tension/pressure
- Stainless Steel Needle – ISO 11070:2014
    - Visual inspection
    - Strength of union of needle tube and needle hub
- Hydrophilic Coated Wire – ISO 11070:2014
    - Visual inspection
    - Hydrodurability
    - Particulate
    - Fracture
    - Flexing
- Stainless Steel Wire – ISO 11070:2014
    - Visual inspection
    - Fracture

  - Flexing
  - Peak Tensile Force
- Packaging integrity – ISO 11607-1:2009/A1:2014 and ISO 11607-2:2006
  - Visual inspection
  - Component position
  - Peel strength
  - Bubble test
  - Dye leak
  - 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.

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 RAILWAY™ Sheathless Access System:

- RAILWAY has a legally-marketed predicate
- RAILWAY has the same Intended Use as the predicate
- RAILWAY incorporates the same fundamental technology as the predicate
- Accepted scientific methods and international standards were used to evaluate substantial equivalence of the RAILWAY System relative to the predicate
- Performance characteristics of the RAILWAY System 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 RAILWAY™ Sheathless Access System is appropriate for its intended use and is substantially equivalent to Glidesheath Slender®.