April 24, 2023

Cordis US Corp.
Wai Morgan
Project Manager, Regulatory Affairs
14201 North West 60th Avenue
Miami Lakes, Florida 33014

Re: K230704
Trade/Device Name: RAIN Sheath™ Tibial Pedal Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 14, 2023
Received: March 15, 2023

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,

Misti L. Malone -S

Misti Malone, PhD
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)*
K230704

Device Name
RAIN Sheath™ Tibial Pedal Introducer

Indications for Use *(Describe)*
RAIN SheathTM Tibial Pedal Introducer is indicated to facilitate placing a catheter through the skin into the lower extremity peripheral vasculature below the knee.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

I. SUBMITTER

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

Contact:
Wai Morgan
wai.morgan@cordis.com

Date Prepared: March 10, 2023

II. DEVICE

Name of Device: RAIN Sheath™ Tibial Pedal Introducer
Common Name: Introducer Sheath
Classification Name: Introducer, Catheter
Product Code: DYB

III. PREDICATE DEVICE

Glidesheath Slender Pedal Tibial Kit cleared on 08/03/2018 under K181237.

Reference Device: RAIN Sheath™ Transradial Introducer cleared on 08/15/2018 under K181592.

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

IV. DEVICE DESCRIPTION

The RAIN Sheath™ Tibial Pedal Introducer is used to facilitate placing a catheter through the skin into the lower extremity peripheral vasculature below the knee.

The RAIN Sheath™ Tibial Pedal Introducer device (hereafter referred as RAIN Sheath™ Pedal) consists of a sheath introducer, a vessel dilator (0.021" guidewire compatible), a stainless-steel entry needle, and a 0.021" guidewire (either stainless steel or nitinol).

The sheath introducer has a lubricious hydrophilic coating, a smooth shoulder

transition to the dilator and low-profile outer diameters (OD). To provide an atraumatic transition between the dilator tip and the 0.021" mini guide wire, the RAIN Sheath™ dilator is tapered at the distal end and the inner diameter (ID) of the dilator has been optimized. The hub is overmolded to the dilator and includes a locking mechanism between the hub of the vessel dilator and the hub of the sheath cannula to facilitate insertion of the product while preventing the vessel dilator from backing out of the cannula.

The RAIN Sheath™ Pedal device is available in four (4) product configurations which differ based on the French sizes (4F and 5F) and specific wire included in the system. RAIN Sheath™ Pedal is a single-use sterile device, sterilized by ethylene oxide.

RAIN Sheath™ device is for professional use in a hospital, catheterization laboratory, or other suitable healthcare facility only.

V. INDICATIONS FOR USE

RAIN Sheath™ Tibial Pedal Introducer is indicated to facilitate placing a catheter through the skin into the lower extremity peripheral vasculature below the knee.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE and REFERENCE DEVICE

RAIN Sheath™ Tibial Pedal Introducer device and the predicate device Glidesheath Slender Pedal Tibial Kit (also referred as "GSS Pedal") facilitate low profile access into the peripheral vasculature below the knee using the same fundamental mechanism of action. Both devices have introducer sheaths with hydrophilic coating which imparts lubricity and facilitates ease of insertion of the device. The dilator component of each device supports the sheath in which it is inserted and dilates the vessel during insertion. The introducer sheath with hydrophilic coating and the tapered dilator which provides a smooth transition between the mini-guidewire and the introducer sheath facilitates atraumatic entry into the artery over a mini-guidewire and minimizes tissue damage.

RAIN Sheath™ Pedal has the following similarities to the GSS Pedal 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 the below the knee procedures

Furthermore, RAIN Sheath™ Tibial Pedal Introducer shares significant similarities with the Cordis RAIN Sheath™ Transradial (reference device). The device components, material composition and the composition of the packaging materials remain the same as that of the RAIN Sheath™ Transradial. The predicate device (GSS Pedal) is offered in 5F size only, whereas the proposed RAIN Sheath™ Pedal will be offered in both 4F and 5F sizes similar to RAIN Transradial.

Based on a thorough analysis of technological characteristics, including design, materials, dimensions, mechanism of action, and clinical use, the RAIN Sheath™ Pedal is substantially equivalent to the predicate device.

VII. NON-CLINICAL TESTS

Performance

The RAIN Sheath™ Pedal device has same intended use, fundamental technology (operating principle), mode of operation, anatomical site of use, clinical utility, as that of the Predicate device, Glidesheath Slender Tibial/Pedal. All components of the RAIN Sheath™ Pedal device come from its reference device, RAIN Sheath Transradial. Both the devices are identical in design, materials, formulation, geometry, manufacturing process, packaging and sterility. Therefore, no design verification was performed on RAIN Sheath™ Pedal to demonstrate the substantial equivalence of the proposed RAIN Sheath™ Tibial/Pedal Introducer.

Design Validation testing was performed to validate that the RAIN Sheath™ Pedal device did not observe any kinking and allowed user to handle the device with reasonable force upon insertion. Additionally, design validation simulated use conditions testing was leveraged from the reference device, RAIN Sheath™ Transradial. The results of the design validation demonstrated that the subject device, RAIN Sheath™ Pedal, is appropriate for its use and is considered substantially equivalent to the predicate device.

Usability

To evaluate critical tasks of the RAIN Sheath™ Pedal device to that of the predicate device, devices were tested in the simulated use condition using a clinically relevant bench top model. All results met the acceptance criteria and demonstrated that the RAIN Sheath™ Pedal device is comparable to its predicate device. Therefore, the usability testing performed supports the substantial equivalence of the proposed RAIN Sheath™ Tibial Pedal Introducer device.

Biocompatibility Testing

RAIN Sheath™ Pedal, like the predicate, is an externally communicating device with limited contact duration (≤ 24 hours) with circulating blood. Biocompatibility testing was performed on the currently cleared RAIN Sheath™ Transradial (K181592) 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 (September 2020) and ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. On that basis, the following tests were leveraged from K181592:

- Chemical Characterization
- In vitro Cytotoxicity- MEM Elution

- Sensitization – Guinea Pig Maximization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemocompatibility
- In vitro Hemolysis -Direct/Extract
- Partial Thromboplastin Time (PTT)
- Platelet and Leukocyte Counts
- Complement Activation C3a & SC5b-9 Assay
- In-vivo Thrombogenicity

Based on the biocompatibility testing performed on RAIN Sheath™ Transradial (cleared under K181592), no additional biocompatibility testing for the subject device was performed as both devices have identical materials.

Sterilization

The RAIN Sheath™ Tibial Pedal Introducer was adopted into the same validated ethylene oxide sterilization protocol for the reference device (RAIN Sheath™ Transradial, cleared under K181592) which was previously validated per ISO 11135:2014+A1:2018 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}. Previous evaluations of the ethylene oxide and ethylene chlorohydrin residuals was leveraged from K181592.

Clinical Studies

No clinical studies were deemed necessary to support substantial equivalence.

VIII. CONCLUSIONS

In summary, the RAIN Sheath™ Tibial/Pedal Introducer is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the predicate device, Glidesheath Slender Tibial Pedal Kit.