



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

Re: K181592
Trade/Device Name: RAIN Sheath Transradial
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 15, 2018
Received: June 18, 2018

Dear Ms. Ankita 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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,

**Finn E.
Donaldson -S**

Digitally signed by Finn E. Donaldson -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
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cn=Finn E. Donaldson -S
Date: 2018.08.15 07:26:59 -04'00'

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K181592

Device Name

RAIN Sheath Transradial

Indications for Use (Describe)

RAIN Sheath Transradial is indicated to facilitate placing a catheter through the skin into a radial artery.

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

I. SUBMITTER

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

Contact:
Ankita Phophalia
Cordis Corporation
1820 McCarthy Boulevard
Milpitas, CA 95035 USA
Tel: (408) 273-3228
Fax: (408) 955-0704

Date Prepared: June 15, 2018

II. DEVICE

Name of Device: **RAIN Sheath™ Transradial**
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

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

IV. DEVICE DESCRIPTION

RAIN Sheath™ Transradial is indicated to facilitate placing a catheter through the skin into a radial artery.

Each RAIN Sheath™ device consists of a sheath introducer, a vessel dilator (0.021" guidewire compatible), an IV cannula needle and/or a bare access needle, and a 45 cm 0.021" guidewire (either bare or hydrophilic). The device configurations with the hydrophilic guidewire contain only the IV cannula needle whereas device configurations with the bare wire contain only the bare needle.

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. RAIN Sheath™ device is available in sixteen (16) product configurations which differ based on French size and length, and the specific wire and needle included in the system, as indicated in the table below. It is offered in French sizes of 4F, 5F, 6F and 7F, with lengths of 10 cm and 16 cm. RAIN Sheath™ device 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.

Catalog Code	0.021" Mini Guidewire	Needle	French Size and Length
506410S	Bare	Bare needle	4 F, 10 cm
506416S			4 F, 16 cm
506510S			5 F, 10 cm
506516S			5 F, 16 cm
506610S			6 F, 10 cm
506616S			6 F, 16 cm
506710S			7 F, 10 cm
506716S			7 F, 16 cm
506410H	Hydrophilic	IV cannula	4 F, 10 cm
506416H			4 F, 16 cm
506510H			5 F, 10 cm
506516H			5 F, 16 cm
506610H			6 F, 10 cm
506616H			6 F, 16 cm
506710H			7 F, 10 cm
506716H			7 F, 16 cm

The materials of construction of the RAIN Sheath™ device components are as follows:

RAIN Sheath™ Transradial Materials of Construction		
Component	Materials	Patient Contact
Sheath Introducer	Nylon, Pebax, Barium Sulfate, color concentrate, hydrophilic coating, PTFE, Polyethylene, Silicone	Direct (≤ 24hr)
Dilator	Nylon, HDPE, Barium sulfate, color concentrate	Direct (≤ 24hr)
Bare Wire	Stainless steel	Direct (≤ 24hr)
Hydrophilic Wire	Nitinol, Tungsten, hydrophilic coating	Direct (≤ 24hr)
Bare Needle	Stainless steel, Polyethylene	Direct (≤ 24hr)
IV Cannula Needle	Stainless steel, MABS, Polypropylene, FEP	Direct (≤ 24hr)

V. INDICATIONS FOR USE

RAIN Sheath™ Transradial is indicated to facilitate placing a catheter through the skin into a radial artery.

The Indications for Use statement for RAIN Sheath™ is identical to that of the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

RAIN Sheath™ device and the predicate device facilitate low profile access into the radial artery 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 radial insertion. The introducer sheath with hydrophilic coating and the tapered dilator which provides a smooth transition between the guidewire and the introducer sheath facilitates atraumatic entry into the radial artery over a guide wire and minimizes tissue damage.

RAIN Sheath™ 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

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

VII. PERFORMANCE DATA

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

Biocompatibility Testing

RAIN Sheath™, like the predicate, is an externally communicating device with limited contact duration (≤ 24 hours) with circulating blood. Biocompatibility testing was performed for RAIN Sheath™ 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 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, RAIN Sheath™ is biocompatible for its intended use:

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

Sterilization

The sterilization cycle used to sterilize RAIN Sheath™ 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, *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 RAIN Sheath™ Transradial 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 RAIN Sheath™ device per applicable sections of the indicated standards and/or validated internal test methods:

- Sheath Introducer – ISO 11070:2014, USP 788 and internal test methods
- Dilators – ISO 11070:2014 and internal test methods
- IV Cannula Needle – ISO 10555-1:2013 and ISO 10555-5:2013
- Stainless Steel Needle – ISO 11070:2014
- Hydrophilic Coated Wire – ISO 11070:2014
- Stainless Steel Wire – ISO 11070:2014
- Packaging integrity – ISO 11607-1:2009/A1:2014 and ISO 11607-2:2006

The passing results for the testing provide reasonable assurance that the subject device has been designed to meet its intended use.

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 of bench testing.

VIII. CONCLUSIONS

The information presented in this Premarket Notification demonstrates the following for the RAIN Sheath™ Transradial:

- RAIN Sheath™ has a legally-marketed predicate
- RAIN Sheath™ has the same Intended Use as the predicate
- RAIN Sheath™ incorporates the same fundamental technology as the predicate
- Accepted scientific methods and international standards were used to evaluate substantial equivalence of the RAIN Sheath™ device relative to the predicate
- Performance characteristics of the RAIN Sheath™ device are equivalent to the predicate device

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 RAIN Sheath™ Transradial is appropriate for its intended use and is substantially equivalent to Glidesheath Slender®.