May 30, 2019

Freudenberg Medical MIS, Inc
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K190628
Trade/Device Name: FlexSeal Introducer Sheath with Hydrophilic Coating
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: May 21, 2019
Received: May 22, 2019

Dear Mark Job:

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

Kenneth Cavanaugh
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)*
K190628

Device Name
FlexSeal™ Introducer Sheath with Hydrophilic Coating

Indications for Use *(Describe)*
The FlexSeal® Introducer Sheath with Hydrophilic Coating is intended to be placed in the peripheral vasculature to provide a conduit for the introduction of diagnostic or interventional devices, and to minimize blood loss associated with such insertions.

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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1 510(K) SUMMARY

1.1 ADMINISTRATIVE INFORMATION

Date of Summary Preparation: May 29th, 2019

1.2 CONTACT INFORMATION

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1.3 DEVICE INFORMATION

Trade Name	FlexSeal™ Introducer Sheath with Hydrophilic Coating
Common Name	Introducer Sheath
Classification Name	Catheter Introducer
Classification Regulation	870.1340
Class	II
Panel	Cardiovascular
Product Code	DYB
Previous Submissions	None

1.4 510(K) TYPE AND REASON FOR SUBMISSION

This 510(k) is a special 510(k) and is submitted to obtain marketing clearance for a line extension of the FlexSeal device family.

1.5 PREDICATE DEVICE

The FlexSeal Introducer Sheath with Hyrdophilic Coating is substantially equivalent to the FlexSeal Introducer Sheath with Hydrophilic Coating devices (K161659).

1.6 DEVICE DESCRIPTION

The FlexSeal Introducer set contains the following disposable components:

- One sterile introducer sheath with an active spring loaded hemostatic valve
- One sterile radiopaque dilator

The FlexSeal Introducer set consists of an introducer sheath with hydrophilic coating and a dilator. The device size is 21Fr with a 56 cm shaft. An active hemostatic valve is integrated into the sheath. A Ring Lock at the proximal end of the device assists with the control of the hemostatic valve.

1.7 INDICATIONS FOR USE

The FlexSeal™ Introducer Sheath with Hydrophilic Coating is intended to be placed in the peripheral vasculature to provide a conduit for the introduction of diagnostic or interventional devices, and to minimize blood loss associated with such insertions.

1.8 TECHNOLOGICAL CHARACTERISTICS

The sheath shaft's external surface has a hydrophilic coating to facilitate introduction into the cardiovascular system. The introducer sheath has a tapered leading tip and a marker band within the tip for visualization. Proximal to the shaft is a housing that contains an extension tube with a 3-way stopcock. The hub is an active valve which can be manually open for device introduction to provide hemostasis and minimize blood loss. These features are the same as the predicate.

The dilator has a tapered distal tip. Its lumen is compatible with a 0.035" guidewire. This is the same as the predicate.

The Ring Lock at the proximal end of the hub allows the user to keep the valve in partially open positions without the need to manually hold the valve open. This feature is not present on the predicate, but does not change the function of the device. The Ring Lock is an extra feature to assist the physician when using the device, but if it is not engaged, the device still functions the same as the predicate device.

1.9 PERFORMANCE DATA

The FlexSeal has been tested to meet the device intended use and to ensure conformance to the product specifications.

The FlexSeal has been tested and meets all its physical and performance specifications on the bench including:

- Visual surface inspection
- Dimensions

- Guidewire compatibility
- Leakage
- Kink resistance
- Bond tensile strength
- Hydrophilic coating integrity
- Luer compliance
- Cracking pressure
- USP particulate test
- Packaging tests
- Distribution tests
- Simulated Use
- Shelf Life Testing

The following tests were leveraged from the predicate device:

- Radiopacity
- Dilator hub dimensions
- Corrosion

In addition, the FlexSeal was tested for biocompatibility per ISO 10993-1 for short duration contact with circulating blood (<24 hours). Only cytotoxicity was repeated for the subject device.

Family of Biocompatibility Tests Performed	Results
Cytotoxicity	Meets Requirements
Sensitization	Same as Predicate
Irritation/Intracutaneous Reactivity	Same as Predicate
Systemic (Acute) Toxicity	Same as Predicate
Genotoxicity	Same as Predicate
Hemocompatibility	Same as Predicate

The device is sterilized by ethylene oxide to an SAL 10^{-6} level. These performances are similar to that described by the predicate device.

The conclusions drawn from the nonclinical tests that demonstrate that the subject device's performance was substantially equivalent to the predicate device.

1.10 SUBSTANTIAL EQUIVALENCE

The FlexSeal is substantially equivalent to the FlexSeal devices (K161659). It has the same intended use for facilitating the introduction of devices into the cardiovascular system and to

minimize blood loss. The conclusions drawn from the nonclinical tests that demonstrate that the subject device's performance was substantially equivalent to the predicate device.

1.11 CONCLUSION

Based on the test data and the same intended use, the FlexSeal is found to be substantially equivalent to its predicate.