DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 15, 2016

Libra Medical Inc.
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K161659
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: June 14, 2016
Received: June 16, 2016

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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Brian D. Pullin -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161659

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.

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1 510(K) SUMMARY

1.1 ADMINISTRATIVE INFORMATION

Date of Summary Preparation: July 15, 2016

1.2 NAME/ADDRESS OF SPONSOR

Belinda Jackson
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Jeffersonville, Indiana 47130
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1.3 CONTACT INFORMATION

Primary Submission Contact	Sew-Wah Tay, PhD Regulatory Consultant, Libra Medical Inc.
Secondary Submission Contact	Ming-Cheng Chew Regulatory Consultant, Libra Medical Inc.

1.4 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

1.5 510(K) TYPE AND REASON FOR SUBMISSION

This 510(k) is a traditional 510(k) and is submitted to obtain marketing clearance for a new device – the FlexSeal™ Introducer Sheath with Hydrophilic Coating.

1.6 PREDICATE DEVICE

The FlexSeal™ Introducer Sheath with Hydrophilic Coating is substantially equivalent to the DrySeal devices (K121234).

1.7 DEVICE DESCRIPTION

The FlexSeal™ Introducer Sheath with Hydrophilic Coating contains the following disposable components:

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

The FlexSeal™ Introducer Sheath with Hydrophilic Coating consists of an introducer sheath with hydrophilic coating and a dilator. The devices sizes are 14F, 16F and 18F. Three different lengths (20 cm, 28 cm and 35 cm) are available for each FlexSeal introducer size. An active hemostatic valve is integrated into the sheath.

1.8 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.

1.9 TECHNOLOGICAL CHARACTERISTICS

The sheath shaft's is radiopaque and its external surface has a hydrophilic coating to facilitate introduction into the cardiovascular system. The introducer sheath is radiopaque and has a tapered leading tip and a marker band within the tip for visualization.

The distal end of the sheath features a platinum/iridium radiopaque marker for visualization under fluoroscopy. 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. The dilator is radiopaque with a tapered distal tip. It's lumen is compatible with a 0.035" guidewire.

The technological characteristics of the device is similar to the predicate device. Both device are introducer sheaths with radiopaque shaft with hydrophilic coating and a hemostatic valve designed specifically to minimize blood loss. The design of the hemostatic valves are different but this difference does not affect the safety or efficacy of the device.

1.10 PERFORMANCE DATA

The FlexSeal™ Introducer Sheath with Hydrophilic Coating has been tested to meet the device intended use and to ensure conformance to the product specifications.

The FlexSeal™ Introducer Sheath with Hydrophilic Coating has been tested and meets all its physical and performance specifications on the bench including:

- Visual surface inspection
- Dimensions
- Radioapacity visualization
- Guidewire compatibility
- Hemostasis – valve leakage

- Kink resistance
- Bond tensile strength
- Hydrophilic coating integrity
- Luer compliance
- Cracking pressure
- USP particulate test
- Packaging tests
- Distribution tests
- Usability studies

In addition, the FlexSeal™ Introducer Sheath with Hydrophilic Coating was tested for biocompatibility per ISO 10993-1 for short duration contact with circulating blood (<24 hours). The testing showed that the device meets all the requirements. The list of tests performed is provided below.

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

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

1.11 SUBSTANTIAL EQUIVALENCE

The FlexSeal™ Introducer Sheath with Hydrophilic Coating is substantially equivalent to the DrySeal device (K121234). The technological characteristics of the device is similar to the predicate device. Both device are introducer sheaths with radiopaque shaft with hydrophilic coating and a hemostatic valve designed specifically to minimize blood loss. The design of the hemostatic valves are different but this difference does not affect the safety or efficacy of the device.

The conclusions drawn from the nonclinical testing demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device (DrySeal devices (K121234)).

1.12 CONCLUSION

Based on the test data the FlexSeal™ Introducer Sheath with Hydrophilic Coating is found to be substantially equivalent to its predicate.