



March 7, 2019

Endophys Holdings LLC
% Gregory Sachs
President
Sachs & Associates, Inc
5116 Birch Road
Minnetonka, Minnesota 55345

Re: K190098

Trade/Device Name: Endophys Pressure Sensing Sheath Kit – 8F
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB, DXO
Dated: January 18, 2019
Received: January 22, 2019

Dear Gregory Sachs:

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,

Shawn W. Forrest -S

2019.03.07 22:26:06 -05'00'

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)

K190098

Device Name

Endophys Pressure Sensing Sheath Kit- 8F

Indications for Use (Describe)

The Endophys Pressure Sensing Sheath Kit (Endophys Pressure Sensing Sheath and vessel dilator) is intended to facilitate the introduction of diagnostic and interventional devices into the vasculature and to continuously measure blood pressure during the procedure when used with the Endophys Blood Pressure Monitor. Together, the Pressure Sensing Sheath and the Blood Pressure Monitor comprise the Endophys Pressure Sensing Access System (PSAS™).

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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510(k) Summary
Endophys Pressure Sensing Sheath Kit

I. SUBMITTER

Endophys Holdings, LLC
Thanksgiving Tower, Suite 3500
1601 Elm Street
Dallas, TX 75201

Contact person: Phillip D. Purdy, M.D.
Phone: 214-801-0578
Fax: 214-377-0709
Date prepared: January 18, 2019

II. DEVICE

Name of the device: Endophys Pressure Sensing Sheath Kit
Common of usual name: Introducer Catheter and accessories
Classification name: Catheter Introducer
Regulatory Class: 2
Product Code: DYB (classification); DXO (subsequent)

III. PREDICATE DEVICE

Endophys Pressure Sensing Sheath Kit (K173399)
This predicate has not been subject to a design-related recall

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Endophys Pressure Sensing Sheath Kit is comprised of the Endophys Pressure Sensing Sheath and vessel dilator. The Endophys Pressure Sensing Sheath and accessories are provided sterile (EO).

The Pressure Sensing Sheath ("PSS") is an introducer sheath with an integrated fiber optic pressure transducer. The PSS is provided with a dilator which together make up the Endophys Pressure Sensing Sheath Kit ("PSS Kit"). The PSS Kit is intended to be used only with the Endophys Blood Pressure Monitor ("BPM"), which connects to the PSS and displays the blood pressure measurements. Together with the BPM, the PSS is used to continuously monitor patient blood pressure during procedures requiring vascular access.

The PSS introducer sheath is used to assist vascular access in the same manner as do standard catheter introducers. The PSS introducer sheath has an integrated pressure sensor that provides high resolution, continuous and instantaneous pulse wave hemodynamics to monitor blood pressure.

Together, the Pressure Sensing Sheath and the Blood Pressure Monitor comprise the Endophys Pressure Sensing Access System (PSAS™).

The vessel dilator is used to facilitate insertion of the PSS, and is packaged with the Endophys PSS Kit. Once the PSS has been properly positioned in the vessel, the dilator is removed.

V. INDICATION FOR USE

The Endophys Pressure Sensing Sheath Kit (Endophys Pressure Sensing Sheath and vessel dilator) is intended to facilitate the introduction of diagnostic and interventional devices into the vasculature and to continuously measure blood pressure during the procedure when used with the Endophys Blood Pressure Monitor.

Together, the Pressure Sensing Sheath and the Blood Pressure Monitor comprise the Endophys Pressure Sensing Access System (PSAS™).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Introducer catheters, by nature, are tubular structures intended to provide a pathway for therapeutic and/or diagnostic devices into the human vasculature. Specialized introducer catheters have been developed which incorporate sensors into these devices to allow active monitoring of blood pressure during interventional procedures. Blood pressure monitoring using a fiber optic transducer is the technological principle for both the subject and predicate devices. The technology requires use of a compatible blood pressure monitor to provide this data to the clinician.

At a high level, the subject and predicate device are based on the following same technological elements:

• Product Code • Device Classification Name • 21 CFR Regulation Number • Principle of Operation • Target Population • Anatomical Site • Where Used • Contraindications • Human Factors • Placement • Not Resterilized • Sterilization Method • Method of Blood Pressure measurement	• Pressure Sensor Type • Sensor Location • Pressure Range • Accuracy of Pressure Reading • Calibration • Power Source • Sensor Fiber • Sensor Diaphragm, Pedestal • 2-Part Epoxy • Hemostasis Valve Adapter Assembly • 3-Way Stopcock • Dilator Sheath Connectivity • Dilator Size
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• Instructions For Use • Labeling • Biocompatibility Test Results • Sheath Taper Length • Inside/outside diameter • Suture Ring • Radiopaque Marker • Molded Y-Hub • Hemostasis Valve • Primary Lumen Liner • Secondary Lumen Liner	• Dilator Tube/Extrusions • Dilator Hub Resin • Dilator Hub Ink • Dilator Hub Colorant • Sterile Barrier System • Pouch/Shelf/Shipper Box Label • Outer Jacket • Packaged Sterile • Braided Wire (Encapsulated) • Sheath Size • UV Adhesive
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The following technological differences exist between the subject and predicate device. Please note that a guidewire is not supplied with the proposed device.

• Indications for Use • Components • Sheath Overall Length • Sheath Working Length • Dilator Working Length • Guidewire length • Guidewire width/diameter • Guidewire tip configuration • Guidewire Source • Guidewire Straightener	• Guidewire Wire and Core Material • Guidewire Hoop and Clip • Guidewire Luer Lock • Shelf Life • Primary Barrier Height • Die-Cut Card Height • Shelf Carton Height • Shipping Carton Width
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VII. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence.

- Dimensional Analysis
- Sensor Accuracy
- Guide Wire / Device Compatibility
- Flexibility – Tip Deflection
- Flexibility - Kink Resistance
- Flexibility – Sensor Functionality
- Pouch Peel Strength
- Dilator to Hemostasis Valve Separation Force
- L929 MEM Elution - ISO
- L929 Neutral Red Uptake Test (4 Concentrations) - ISO
- Rabbit Pyrogen Test (Material Mediated – ISO)
- Rabbit Blood Hemolysis Complete ASTM

The modified Endophys Pressure Sensing Sheath met all specified criteria and based on the design verification performance, the conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as

effective, and performs as well as or better than the legally marketed device.

VIII. SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate device is substantially equivalent to the indications for use for the proposed PSS Kit. Furthermore, the PSS Kit has the same intended use, patient population, and anatomical sites as well as similar technological characteristics as the predicate device. The differences in technological characteristics have been analyzed and addressed through testing. Any differences in the technological characteristics between the devices do not raise different questions of safety or effectiveness. Thus, the Endophys Pressure Sensing Sheath Kit is substantially equivalent to the predicate device.

IX. CONCLUSION

The PSS Kit contains a catheter introducer sheath with an integrated fiber optic pressure transducer and dilator for standard interventional procedures. The PSS Kit has the same intended use, patient population, and anatomical sites as well as similar technological characteristics as the predicate device. The differences in technological characteristics have been analyzed and addressed through testing. As such, the PSS Kit is substantially equivalent to the predicate device.

X. SUMMARY

The PSS Kit is substantially equivalent to the predicate device.