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

March 4, 2016

Endophys, Inc.
Rebecca Pine
Consultant
Thanksgiving Tower, Suite 1930
1601 Elm Street
Dallas, Texas 75201

Re: K160272
Trade/Device Name: Endophys Pressure Sensing Sheath Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB, DXO
Dated: January 28, 2016
Received: February 2, 2016

Dear Rebecca Pine:

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 yours,

for Kenneth J. Cavanaugh -S

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

Enclosure

5. Indications for Use Statement

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)*

K160272

Device Name

Endophys Pressure Sensing Sheath Kit

Indications for Use *(Describe)*

The Endophys Pressure Sensing Sheath Kit (Endophys Pressure Sensing Sheath, vessel dilator and guidewire) 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.

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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6. 510(k) Summary

I. SUBMITTER

Endophys, Inc.
Thanksgiving Tower, Suite 1930
1601 Elm Street
Dallas, TX 75201

Contact person: Rebecca K Pine
Phone: (760) 809-5178
Fax: (760) 290.3216
Date prepared: January 28, 2016

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 (K141275)
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, vessel dilator and guidewire. 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 and a guidewire, which together make up the Endophys Pressure Sensing Sheath Kit ("PSS Kit"). The PSS Kit is intended to be used 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. The PSS introducer sheath is intened only for connectin with the Endophys Blood Pressure Monitor.

The 6F 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.

The guidewire is J tipped, 50cm (length), 0.89mm (diameter), and is used to assist in the placement of the Dilator/PSS Introducer Sheath through the skin and into the vasculature. Once the Dilator and Introducer are positioned over the Guidewire, the Guidewire is removed through the Dilator.

V. INDICATIONS FOR USE

The Endophys Pressure Sensing Sheath Kit (Endophys Pressure Sensing Sheath, vessel dilator and guidewire) 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.

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 catheter 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 devices are based on the following same technological elements:

- Compatibility with Endophys Blood Pressure Monitor
- Hemostasis valve- to prevent blood leakage during the procedure
- Suture ring- aid in placement
- Fiber optic pressure transducer
- Visibility under radiographic imaging
- Locking sheath hub

The following technological differences exist between the subject and predicate devices:

- Modify sheath hub taper for ease of dilator insertion
- Increase in sheath inside diameter from 0.82 to 0.89
- Incorporate locking dilator hub feature
- Modify dilator/sheath dimensions to minimize sheath/dilator profile including a reduction in sheath shaft length and increased taper

VII. PERFORMANCE DATA

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

- Luer verification
- Dimensional verification
- Accessories compatibility
- Radiopacity
- Tip deflection
- Kink resistance
- Sensor functionality
- Tip compression
- Liquid leakage
- Separation force
- Corrosion resistance

The modified Endophys Pressure Sensing Sheath met all specified criteria and did not raise new safety or performance questions. Based on the design verification performance the modified Endophys Pressure Sensing Sheath Kit was found to have the a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSIONS

The design testing performed as a part of the applied Design Controls to the modified Endophys Pressure Sensing Sheath Kit demonstrated that the performance of the modified device is equal to the legally marketed Endophys Pressure Sensing Sheath Kit.