**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

September 26, 2016

Endophys Holdings, LLC
Rebecca Pine
Official Correspondent
1601 Elm Street
Dallas, Texas 75201

Re: K160945
Trade/Device Name: Endophys Blood Pressure Monitor, Model 651
Regulation Number: 21 CFR 870.1110
Regulation Name: Blood Pressure Computer
Regulatory Class: Class II
Product Code: DSK
Dated: August 23, 2016
Received: August 24, 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

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)*
K160945

Device Name
Endophys Blood Pressure Monitor (Model 651)

Indications for Use *(Describe)*
The Endophys Blood Pressure Monitor Model 651 is intended for use in a catheterization laboratory to continuously provide systolic, diastolic and mean blood pressure based on the output of the Endophys Pressure Sensing Sheath in patients undergoing therapeutic and/or diagnostic procedures involving percutaneous vascular access.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 6. 510(k) Summary

I. SUBMITTER

Endophys Holdings, LLC
Thanksgiving Tower, Suite 1930
1601 Elm Street
Dallas, TX 75201

Contact person: Rebecca K Pine
Phone: (760) 809-5178
Date prepared: March 30, 2016

II. DEVICE

Name of the device: Endophys Blood Pressure Monitor, Model 651
Common of usual name: Blood Pressure Monitor
Classification name: Computer, Blood Pressure
Regulatory Class: 2
Product Code: DSK

III. PREDICATE DEVICE

Endophys Blood Pressure Monitor (K141615)
This predicate has not been subject to a design-related recall
IntelliVue Patient Monitors MX400, MX450, MX500 and MX550 (K141015) [ reference predicate]
This predicate has not been subject to a design-related recall

IV. DEVICE DESCRIPTION

The Endophys Blood Pressure Monitor Model 651 is a blood pressure computer that computes and continuously displays systolic, diastolic and mean blood pressure values. The BPM obtains an optical signal from the Endophys Pressure Sensing Sheath, which is a standalone catheterization sheath that is inserted percutaneously during intravascular diagnostic or interventional procedures. The BPM converts the optical transducer data to electrical signals and displays blood pressure measurements.

The Endophys Blood Pressure Monitor Model 651 is powered by a standard AC power adapter. The Endophys Blood Pressure Monitor Model 651 is used outside of the sterile environment and has standard alerts and alarms.

The Endophys Blood Pressure Monitor Model 651 has an operating pressure range of 0-300 mmHg with an accuracy of ±2mmHg or ±4% of the reading, whichever is greater.

V. INDICATIONS FOR USE

The Endophys Blood Pressure Monitor Model 651 is intended for use in a catheterization laboratory to continuously provide systolic, diastolic and mean blood pressure based on the output of the Endophys Pressure Sensing Sheath in patients undergoing therapeutic and/or diagnostic procedures involving percutaneous vascular access..

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Blood Pressure Monitors, by nature, are instruments intended to provide clinicians with the physiological blood pressure of patients reported in milligrams of mercury (mmHg). Specialized computer based instruments have been developed which allow active monitoring of blood pressure during interventional procedures. Blood pressure monitoring using a fiber optic communication is the technological principle for both the subject and predicate devices. The technology requires use of a compatible intravascular pressure sensing sheath to provide this data to the clinician.

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

- Calculates and displays hemodynamic (invasive blood pressure) data when attached to a compatible intravascular pressure sensing device (Endophys Pressure Sensing Sheath)
- Optical signal (fiber optic) measurement of blood pressure
- Pressure measurement range 0-300 mmHg
- Pressure accuracy: System accuracy:± 2 mmHg or ± 4% of the reading, whichever is greater

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

- Plastic mode mixer
- USB Port feature
- Patient Monitor Interface port

VII. PERFORMANCE DATA

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

- Functional Testing
- Electrical Safety (IEC 60601-1)
- Electromagnetic compatibility (IEC 60601-1-2)
- Safety and Essential Performance for Invasive blood pressure monitoring equipment (IEC 60601-2-34)

The modified Endophys Blood Pressure Monitor Model 651 met all specified criteria and did not raise new safety or performance questions. Based on the design verification performance the modified Endophys Blood Pressure Monitor was found to have a safety and effectiveness profile that is similar to the predicate device.

## VIII. CONCLUSIONS

The testing performed for the modified Endophys Blood Pressure Monitor Model 651 demonstrated that the performance of the modified device is equal to the legally marketed Endophys Blood Pressure Monitor.