DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 7, 2015

Endophys, Inc.
% Ronald Warren
Regulatory Consultant for Endophys, Inc
Experien Group, LLC
755 N. Mathilda, Ave, Suite 100
Sunnyvale, California 94085

Re: K141615
Trade/Device Name: Endophys Blood Pressure Monitor
Regulation Number: 21 CFR 870.1110
Regulation Name: Blood Pressure Computer
Regulatory Class: Class II
Product Code: DSK
Dated: December 5, 2014
Received: December 9, 2014

Dear Ronald Warren,

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,

Melissa A. Torres -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)* K141615

Device Name
Endophys Blood Pressure Monitor

Indications for Use *(Describe)*
The Endophys Blood Pressure Monitor 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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."

510(k) SUMMARY

510(k) Notification K_____

GENERAL INFORMATION

Applicant:
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1601 Elm Street
Dallas, TX 75201
U.S.A.
Phone: 1-214-871-3320

Contact Person:
Ronald S. Warren
Regulatory Consultant for Endophys, Inc.
Experien Group, LLC
755 N. Mathilda Ave, Suite 100
Sunnyvale, CA 94085
U.S.A.
Phone: 1-408-505-3926
FAX: 1-408-400-0865

Date Prepared: June 13, 2014

DEVICE INFORMATION

Trade Name:
Endophys Blood Pressure Monitor

Generic/Common Name:
Blood Pressure Computer

Classification:
Class II, 21 CFR§870.1110

Product Code:
DSK, Computer, Blood Pressure

PREDICATE DEVICES

- Radi Medical Systems AB (now St. Jude Medical AB) RadiAnalyzer Xpress (K092105)
- Acist Medical Systems Rapid Exchange (RXi) System and Navvus Catheter (K132474)

510(k) SUMMARY

INDICATIONS FOR USE

The Endophys Blood Pressure Monitor 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.

PRODUCT DESCRIPTION

The Endophys Blood Pressure Monitor ("BPM") 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 stand-alone 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.

SUBSTANTIAL EQUIVALENCE

The indications for use for the Endophys Blood Pressure Monitor are substantially equivalent to the indications for use for the predicate devices. The Endophys Blood Pressure Monitor has the same intended use and similar technological characteristics as those of the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Endophys Blood Pressure Monitor is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary testing was conducted on the BPM to support a determination of substantial equivalence to the predicate devices. Testing of the BPM included design verification testing, electrical safety testing, and electromagnetic compatibility testing. The collective results of the testing demonstrate that the BPM meets the established specifications necessary for consistent performance during its intended use. In addition, the testing demonstrates that the BPM does not raise new questions of safety or effectiveness when compared to the predicate devices.

CONCLUSION

The BPM has the same intended use and similar technological characteristics as do the predicate devices. The differences in technological characteristics have been analyzed and addressed through performance testing. As such, the BPM is substantially equivalent to the predicate devices.

SUMMARY

The Endophys Blood Pressure Monitor is substantially equivalent to the predicate devices.