November 3, 2023

Endophys Technologies LLC
% Mike Winegar
Principal
Winegar Consulting, Inc.
7829 Ithaca Ln N
Maple Grove, Minnesota 55311

Re: K231586
Trade/Device Name: Endophys Blood Pressure Monitor Model BPM-30
Regulation Number: 21 CFR 870.1110
Regulation Name: Blood Pressure Computer
Regulatory Class: Class II
Product Code: DSK
Dated: May 30, 2023
Received: May 31, 2023

Dear Mike Winegar:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 6/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231586

Device Name

Endophys Blood Pressure Monitor Model BPM-30

Indications for Use *(Describe)*

Indications for Use

The Endophys Blood Pressure Monitor Model BPM-30 is intended to continuously provide systolic, diastolic and mean blood pressure based on the output of the Endophys PSS3 Pressure Sensing Sheath in patients undergoing therapeutic and/or diagnostic procedures involving percutaneous vascular access. The Endophys Blood Pressure Monitor Model BPM-30 monitor is additionally intended for use in transport situations within hospital environments.

Type of Use *(Select one or both, as applicable)*

X 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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Measuring physiology where it happens.

510(k) SUMMARY

Applicant	Endophys Technologies, LLC 1933 E Levee St, Suite B Dallas, TX 75207
Contact Person	Mike Winegar Principal Winegar Consulting, Inc. 763-639-0700 mwinegar@comcast.net
Summary Date	September 29, 2023
Proprietary Name	Endophys Blood Pressure Monitor model BPM-30
Classification	Class II
Classification Name	Computer, Blood-Pressure
Regulation Number	21 CFR 870.1110
Product Code	DSK
Predicate Device	The Endophys Blood Pressure Monitor model BPM-30 is substantially equivalent to the currently marketed Endophys Blood Pressure Monitor model BPM-20 (K160945)

Device Description:
The Endophys BPM-30 Blood Pressure Monitor is an electronic device that provides compatibility between a physiological fiber optic blood pressure sensor (transducer) and conventional invasive arterial blood pressure inputs to a standard physiological patient monitor. The device converts the optical transducer data to electrical signals that are interpreted by a conventional patient monitor and/or are displayed directly on the BPM-30. The BPM-30 accurately emulates a fluidic arterial blood pressure transducer and supplies electrical signals to its output that are indistinguishable from a conventional fluidic blood pressure transducer.

The BPM-30 is implemented as a self-contained unit that has a fiber optic transducer connection as an input source and communicates with a patient monitor as its output. The BPM acts to directly emulate the electrical interface characteristics of conventional fluidic blood pressure transducers (that patient monitors are compatible with) while providing much more precise blood pressure data derived from a fiber optic transducer placed within an artery. Electrically emulating a conventional fluidic transducer uniquely allows a fiber optic pressure sensor to be used with a wide variety of existing physiological patient monitors without modification of those monitors. Systolic, diastolic, and mean blood pressure values are also displayed directly on the BPM-30 every four seconds.

The BPM-30 is powered by a standard AC power adapter. The BPM-30 also has an internal battery supply that will automatically recharge and maintain operation during brief (up to 30 minutes) power interruptions. The BPM-30 is used outside of the sterile environment and has standard alerts and alarms.

The BPM-30 has an operating pressure range of -30 to 300 mmHg with an accuracy of ±1 mmHg plus ±1% of reading for pressures ≤ 50 mmHg and within ±3% of reading for pressures ≥ 50 mmHg

Intended Use:
The Endophys BPM-30 Blood Pressure Monitor is meant to be used in minimally invasive vascular procedures and critical patient care situations where the accuracy and timeliness of arterial blood pressure measurements are important. It supports fiber optic transducers that are incorporated into the Endophys PressureSense™ hydrophilic coated Pressure Sensing Sheath (PSS3).

When used with the Endophys Pressure Sensing Sheath, the BPM-30 is designed to provide continuous and accurate systolic, diastolic and mean blood pressure data with no other catheter, pressure transducer or fluid line required.

Indications for Use:

The Endophys Blood Pressure Monitor Model BPM-30 is intended to continuously provide systolic, diastolic and mean blood pressure based on the output of the Endophys PSS3 Pressure Sensing Sheath in patients undergoing therapeutic and/or diagnostic procedures involving percutaneous vascular access. The Endophys Blood Pressure Monitor Model BPM-30 monitor is additionally intended for use in transport situations within hospital environments.

Summary of Technical Characteristics as Compared to 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 PSS3 Pressure Sensing Sheath)
- Optical signal (fiber optic) measurement of blood pressure
- Pressure measurement range -30 to 300 mmHg
- Pressure accuracy: System accuracy ±1 mmHg plus ±1% of reading for pressures ≤ 50 mmHg and within ±3% of reading for pressures ≥ 50 mmHg

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

- Modification of device design to be compatible with FISO Technologies Inc. Fabrey-Perot fiber optic pressure sensors and circuitry incorporated into the Endophys Pressure Sensing Sheath (PSS3)
- Combine the functionality of the daughterboard onto the main circuit board, which were separate in the predicate device
- Addition of an internal battery supply that will automatically recharge and maintain operation during brief (up to 30 minutes) patient transport or power interruptions

Performance Data

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

- Software Verification
- Electrical Safety and Essential Performance Testing (IEC60601-1, IEC60601-1-8, IEC60601-2-34)
- EMC Testing (IEC60601-1-2)
- Packaging Design Verification
- Package, Device, and Labeling Inspection
- Functional Testing

The modified Endophys Blood Pressure Monitor 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 the safety and effectiveness profile that is similar to the predicate device.

Conclusion:

Endophys believes the proposed BPM-30 Blood Pressure Monitor is substantially equivalent to the legally marketed predicate device. The indications for use, methods of operation, design and materials used are either identical or substantially equivalent to the existing legally marketed predicate product.