K110347 Page 1/2

MAR 16 2011

510(k) Summary

Submitted by:

Jim Ferguson
Quality Systems Manager
Cook Vascular, Incorporated
1186 Montgomery Lane
Vandergrift, Pa 15690
724-845-8621, XT 2227
April 10, 2006

Device:

Trade name: **Cook Vascular, Inc. Blood Flow Monitor – Model DP-M350**

Proposed Classification: **Cardiovascular Blood Flow Meter, 870.2100**

Predicate Devices:

The **Cook Vascular, Inc. Blood Flow Monitor – Model DP-M350** is the same in terms of intended use, materials of construction and technology characteristics to the predicate devices that have been found substantially equivalent.

Device Description:

The proposed device is monitor unit that generates a (20 MHz) signal and conducts it to an attached probe that contains a piezo-electric crystal which transmits and then receives Doppler frequency sound waves. The returning signal is amplified and projected via the proposed monitoring unit as an audible output. The monitor unit has two input channels and also provides an adjunct visible (LED) indicator that is used as a complimentary information source to the primary audible indicator. The predicate device was submitted as a system, the proposed device is only the monitoring unit.

Substantial Equivalence:

This device will be manufactured to specified process controls and a Quality Assurance program. This device will undergo validated packaging operations indicative of devices currently manufactured by Cook Vascular. Being the same as the predicate devices in respect to indication for use and no changes in the fundamental scientific technology, this device meets the requirements for section 510(k) substantial equivalence. It is to be noted that this change is only to the monitoring device and will be used with the currently marketed Cook- Swartz Doppler Flow Probes.

The only changes to the device are an added visual display, software controls for visual indicator, on/off switch, channel selector and volume. Additionally a chargeable battery system has been added.

Test Data:

The **Cook Vascular, Inc. Blood Flow Monitor – Model DP-M350** was subjected to the flowing tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Electrical Safety Testing
2. Battery Testing
3. EMC Testing
4. Software Validation
5. Shock/Vibration Testing
6. Mechanical Validation
7. Packaging Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a **Blood Flow Monitor**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Cook Vascular, Inc.
% Mr. Jim Ferguson, Jr.
Quality Systems Manager
1187 Montgomery Lane
Vandergrift, Pennsylvania 15690

MAR 16 2011

Re: K110347
Trade/Device Name: Cook Vascular, Inc. Blood Flow Monitor – Model DP-M350
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular blood flowmeter
Regulatory Class: II
Product Code: DPW, ITX, JOP
Dated: February 3, 2011
Received: February 16, 2011

Dear Mr. Ferguson:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K110347

Device Name: **Cook Vascular, Inc. Blood Flow Monitor – Model DP-M350**

Indications for Use:

The Cook Vascular Blood Flow Monitor - Model DP-M350 is intended for monitoring blood flow in vessels intraoperatively, and following micro-vascular procedures, re-implantation, and free-flap transfers. The Swartz Doppler Flow Probe is supplied sterile and is intended for one-time use.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110347