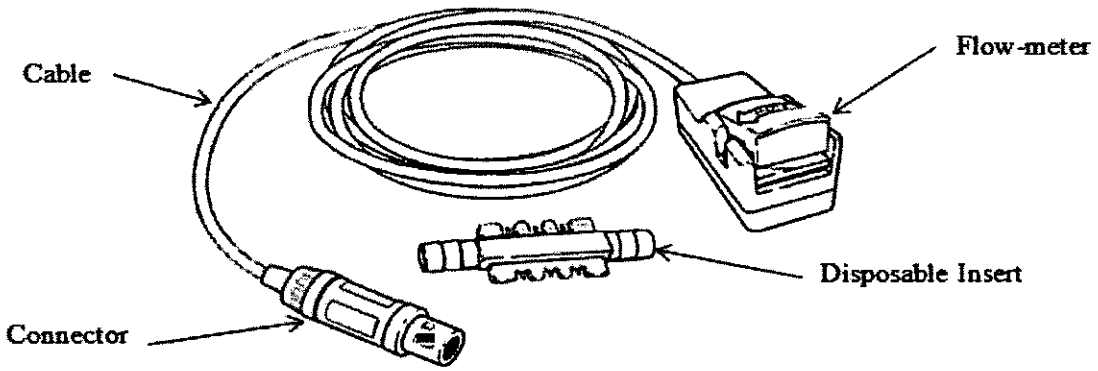
APR 1 0 2014

510(k) Summary of Safety and Effectiveness

Date Prepared:	December 18, 2013
Applicant:	Medtronic, Inc. Medtronic Perfusion Systems 7611 Northland Drive Brooklyn Park, MN 55428 **Establishment Registration No. 2184009**
Contact Person:	Rahul Shah Regulatory Operations Specialist Medtronic, Inc. Cardiac and Vascular Group – Structural Heart 8200 Coral Sea Street NE, MVS 83 Mounds View, MN 55112 Phone: (763) 514-9846 Fax: (763) 367-8147 Email: rahul.m.shah@medtronic.com
Trade Name:	Bio-Probe® Blood Flow Transducer
Common Name:	Probe, Blood Flow, Extravascular
Classification Name:	Probe, Blood-Flow, Extravascular
Classification:	Class II, 21 CFR 870.2120
Product Code:	DPT
Name of Predicate Device:	Bio-Probe Blood Flow Transducer (K070286)

Device Description

The Bio-Probe™ Blood Flow Monitoring System consists of a flow transducer and a sterile, single-use insert. The flow transducer consists of a flow-meter, cable and connector. The TX50 (adult) and TX50P (pediatric) transducer models are reusable. The Bio-Probe blood flow monitoring system can be used to measure the patient blood flow during the extracorporeal procedure.



This submission covers the addition of a contraindication for the Bio-Probe Flow Transducer.

"This device used for any other purpose other than for the indicated intended use is the responsibility of the user."

Intended Use

The Bio-Probe® Blood Flow Monitoring System is to be used with an appropriate model Bio-Console™ Extracorporeal Blood Pumping Console to measure directly the blood flow in the extracorporeal perfusion circuit.

Comparison to the Predicate Device

The Bio-Probe Blood Flow Transducer has the same indications for use, technology and performance specifications as the previously cleared Bio-Probe Blood Flow Transducer. The only change to the device is the incorporation of the contraindication statement to be consistent with contraindications in other Medtronic devices in the extracorporeal perfusion circuit.

Summary of Performance Data

Testing was not required for addition of a contraindication statement. Addition of the contraindication statement does not change the indications for use, technology and performance specifications of this device.

Conclusion

Addition of the contraindication statement does not change the indications for use, technology and performance specifications of this device. Therefore the Bio-Probe Blood Flow Transducer is substantially equivalent to the currently marketed predicate devices.

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

April 10, 2014

Medtronic Inc.
Mr. Rahul Shah
Regulatory Operations Specialist
8200 Coral Sea Street Ne
Mounds View, MN 55112 US

Re: K133903
Trade/Device Name: Bio-probe Blood-Flow Transducer, models TX50 (adult) and TX50P (pediatric)
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular blood-flow probe
Regulatory Class: Class II
Product Code: DPT
Dated: February 26, 2014
Received: February 27, 2014

Dear Mr. Shah:

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 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. 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 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,

Kenneth J. Cavanaugh -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133903

Device Name
Bio-Probe Flow Transducer (Adult and Pediatric)

Indications for Use *(Describe)*

The Bio-Probe blood flow monitoring system is to be used with an appropriate model Bio-Console extracorporeal blood pumping console to measure directly the blood flow in the extracorporeal perfusion circuit.

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)*

Kenneth J. Cavanaugh -S