DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 20, 2016

Medtronic, Inc.
Choua Thao
Regulatory Affairs Specialist
7611 Northland Dr.
Brooklyn Park, Minnesota 55428

Re: K160091
Trade/Device Name: Temperature Probe
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: April 19, 2016
Received: April 20, 2016

Dear Choua Thao:

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,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K160091

Device Name
Temperature Probes

Indications for Use *(Describe)*
The temperature probe is intended for use for continuous blood temperature monitoring as measured at a temperature monitoring adapter located within a Medtronic extracorporeal circulation device as specified in the device's instructions for use. The temperature probe is designed for use with a YSI tele-thermometer to monitor and display temperature.

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.

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510(k) Summary
K160091

Date Prepared: May 12, 2016

Submitter:

Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428

Establishment Registration Number: 2184009

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Device Name and Classification

Trade Name:	Temperature Probe
Common Name:	Clinical Electronic Thermometer
Regulation Number:	880.2910
Product Code:	FLL
Product Classification:	Class II

Predicate Device

K100645	Affinity Temperature Probe

Reference Device

K831528	Temperature Probe

Device Description
The temperature probe devices are intended for use with the temperature monitoring adapter of compatible Medtronic devices and the YSI™ tele-thermometer[1]. The probe has a thermistor sensor housed in a stainless steel sheath connected to a 3-m (10-ft) cable, terminating with a 6.35-mm (1/4-in) phono plug.

The temperature probes meet the requirements of IEC 60601-1 when connected to a temperature monitor Class I or Class II device of type "CF."

Indications for Use
The temperature probe is intended for use for continuous blood temperature monitoring as measured at a temperature monitoring adapter located within a Medtronic extracorporeal circulation device as specified in the device's instructions for use. The temperature probe is designed for use with a YSI tele-thermometer to monitor and display temperature.

Comparison to Predicate and Reference Devices
A comparison of the proposed temperature probes to the currently marketed predicate devices (K831528 and K100645) indicates the following similarities:

- Same operating principle
- Same fundamental technological characteristics
    - Substantially equivalent overall device design
    - Substantially equivalent materials
    - Same energy source
- Substantially equivalent intended use/indications

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

Differences	**Impact Discussion**
Use of lead free solder	Testing demonstrated that the change in solder had no impact on operation of the device.
Use of PVC for cable	Testing demonstrated that the change in cable material had no impact on the operation of the device.
Use of RTV (room temperature vulcanization silicone)	Testing demonstrated that the change in adhesive had no impact on the operation of the device.
Use of additional insulation sleeve	Testing demonstrated that the additional insulation sleeve did not negatively impact the operation of the device.

[1] YSI is a trademark of YSI Incorporated.

The following is a comparison table of the proposed temperature probes to the currently marketed predicate devices. The temperature probe devices are substantially equivalent.

Comparison Table – Indications for Use and Physical Specification

Element of Comparison	Reference I – K831528	Reference II – K831528	Predicate – K100645	Current Submission	Substantially Equivalent?
	Temperature Probe	Temperature Probe	Affinity Temperature Probe	Temperature Probe	
	FDA Clearance 30June1983	FDA Clearance 30June1983	FDA Clearance 14September2012		
Models	1384	TP	ATP210	1384, TP, ATP210	
Indications for Use	Reusable temperature probes are designed for continuous temperature measurement and control with monitors specifically designed for use with the 400 Series temperature.	The SciMed Model TP Thermistor Probe is intended to be used with the SciMed Model TMA Temperature Monitoring Adapter and YSI Series 400 equipment. The thermistor is housed in a stainless steel probe, and is connected to a ten foot long shielded cable that is terminated with a ¼ inch phone plug.	The Affinity Temperature Probe is intended for use for continuous blood temperature monitoring as measured at a temperature monitoring adapter located within a Medtronic extracorporeal circulation device as specified in the device's Instructions for Use. The Temperature Probe is designed for use with a YSI™ Tele-thermometer to monitor and display temperature.	The temperature probe is intended for use for continuous blood temperature monitoring as measured at a temperature monitoring adapter located within a Medtronic extracorporeal circulation device as specified in the device's instructions for use. The temperature probe is designed for use with a YSI tele-thermometer to monitor and display temperature.	Yes
Operating Principle	A device that measures differences in resistance and equates that to changes in temperature	A device that measures differences in resistance and equates that to changes in temperature	A device that measures differences in resistance and equates that to changes in temperature	A device that measures differences in resistance and equates that to changes in temperature	Yes
Components	Reusable	Reusable	Reusable	Reusable	Yes

Element of Comparison	Reference I – K831528	Reference II – K831528	Predicate – K100645	Current Submission	Substantially Equivalent?
	Temperature Probe	Temperature Probe	Affinity Temperature Probe	Temperature Probe	
	FDA Clearance 30June1983	FDA Clearance 30June1983	FDA Clearance 14September2012		
Models	1384	TP	ATP210	1384, TP, ATP210	
Sensor	Thermistor Sensor Tip	Thermistor Sensor Tip	Thermistor Sensor Tip	Thermistor Sensor Tip	Yes
Materials	• Thermistor Sensor Tip - Stainless Steel, Brass, Ceramic • Cable – TPE (C-Flex) and Copper • Phono Plug - Brass	• Thermistor Sensor Tip - Stainless Steel, Brass, Ceramic • Cable – TPE (C-Flex) and Copper • Phono Plug - Brass	• Probe tip - Stainless Steel, Brass, Ceramic • Cable – TPE (C-Flex) and Copper • Phono Plug - Brass	• Probe tip – Stainless Steel and Brass • Cable – PVC and Copper • Phono Plug - Brass	Yes
Thermistor	Negative Temperature Coefficient (NTC) Thermistor	Negative Temperature Coefficient (NTC) Thermistor	Negative Temperature Coefficient (NTC) Thermistor	Negative Temperature Coefficient (NTC) Thermistor	Yes
Cable	PVC Insulated 2 conductor twisted pair[2]	PVC Insulated 2 conductor twisted pair	PVC Insulated 2 conductor twisted pair	PVC Insulated 2 conductor twisted pair	Yes
Phono Plug	6.35-mm (1/4-in) phono plug	6.35-mm (1/4-in) phono plug	6.35-mm (1/4-in) phono plug	6.35-mm (1/4-in) phono plug	Yes

[2] Two 24 gauge wires twisted around each other throughout the length of the cable.

Summary of Performance Data
Bench testing was used to demonstrate the performance characteristics of the temperature probe devices. Clinical testing was not required to establish substantial equivalence.

The following performance tests were conducted:

Test	Description	Result
IEC 60601	Ensures the temperature probes meet the requirements of IEC 60601 electrical safety and Electromagnetic compatibility (EMC).	Pass
Temperature Range	Ensures the temperature probes meet the requirements of the system at the extreme temperature ranges.	Pass
Ambient Temperature Environment	Ensures the temperature probes meet the requirements of the system at the normal temperature ranges.	Pass
Accuracy	Accuracy over the entire temperature range specified for the device.	Pass
Precision and Repeatability	Precision and repeatability of measurements over the temperature range specified with the effects of air currents, over the entire temperature range specified.	Pass
Time	Indicate the time required for the device to obtain a steady state reading.	Pass
Life Testing	Ensures the temperature probes meet the requirements of the expected life of the probe.	Pass
Liquid Ingress and Chemical Exposure Testing	Ensures the temperature probes meet the Ingress Protection and cleaning requirements.	Pass

Conclusion
Medtronic has determined that the temperature probe devices described in this submission has shown to be substantially equivalent to the predicate devices.