August 20, 2024

Covidien
Angelica Medina
Regulatory Affairs Specialist
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K240077
Trade/Device Name: Mon-a-Therm™ General Purpose Temperature Probe 400TM (90050, 90044)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: July 16, 2024
Received: July 19, 2024

Dear Angelica Medina:

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,

David Wolloscheck

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors

OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240077

Device Name
Mon-a-Therm™ General Purpose Temperature Probe 400TM (90050, 90044)

Indications for Use *(Describe)*
The Mon-a-Therm™ General Purpose Temperature Probe 400TM is indicated for use in the routine monitoring of temperature in an anesthetized patient. The device is intended primarily for insertion into the esophagus or rectum, although medical judgment may dictate the selection of other anatomical sites such as the nasopharynx for some patients.

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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K240077 - Mon-a-Therm™ General Purpose Temperature Probe 400TM 510(k) Summary

This summary of 510(k) safety and effectiveness information for the Mon-a-Therm™ General Purpose Temperature Probe 400TM is submitted in accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with the requirements of 21 CFR §807.92.

SUBMITTER INFORMATION

Submitted By:

Covidien, llc
6135 Gunbarrel Avenue
Boulder, CO 80301

Date Prepared: August 20th, 2024

Contact Person:

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DEVICE

Trade Name:	Mon-a-Therm™ General Purpose Temperature Probe 400TM
Common Name:	Clinical electronic thermometer
Classification Regulation:	880.2910
Classification Name:	Clinical Electronic Thermometer
Regulatory Class:	Class II
Product Code:	FLL
Review Panel:	General Hospital

PREDICATE DEVICE

Predicate Manufacturer:	Mallinckrodt Critical Care
Predicate Trade Name:	Hi-Lo Temp® General Purpose Temperature Probe
Predicate 510(k):	K874514

DEVICE DESCRIPTION

The subject device of this premarket 510(k) notification is referred to as the Mon-a-Therm™ General Purpose Temperature Probe 400TM throughout this submission.

The Mon-a-Therm™ General Purpose Temperature Probe 400TM is a finished medical device that monitors temperature and are versatile probes that may be used for esophageal, nasopharyngeal or rectal placement.

Features and benefits:

- Fully enclosed sensor helps ensure patient safety
- Satin Slip™ finish for easy insertion
- Compatible with most multifunction patient monitors. Refer to **Table 1:** Summary of Mon-a-Therm™ 400 Series Thermistor Interface Cables.

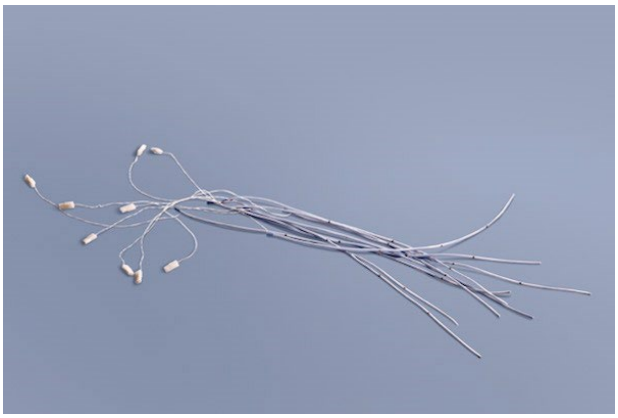

Figure 1: Illustration of subject device Mon-a-Therm™ General Purpose Temperature Probe 400TM

The Mon-a-Therm™ General Purpose Temperature Probe 400TM is packaged individually as a sterile, single-use device and is available in the following sizes: 9 Fr 100/case CFN 90050 and 12 Fr 100/case, CFN 90050.The device and its packaging are not made with natural rubber latex or phthalates. The type of probe and device size are designated on the unit package.

The Mon-a-Therm™ General Purpose Temperature Probe 400TM components are illustrated in **Figure 2.**

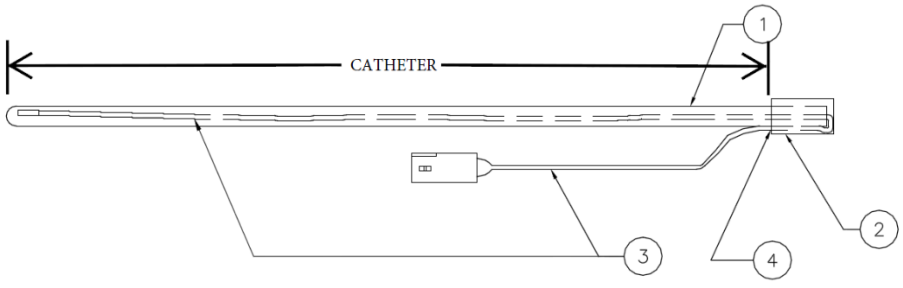

Figure 2: Illustration of Subject Device Components

1. Tube Blue
2. Sleeve GP
3. Thermistor Assembly
4. Slurry Mixture

The structure of Mon-a-Therm™ General Purpose Temperature Probe 400TM is illustrated in **Figure 3** below. The tip of the probe is sealed with PVC and silicone at the end of the thermistor which is where the sealed tube directly contacts the mucosa as shown in **"Detail A"**.

A temperature probe is located near the distal tip. Refer to **Figure 3:** Structure of Subject Device. The catheter of the subject device features a frosted external surface, referred to as Satin Slip surface. This specialized surface coating extends across the entire external area of the subject device.

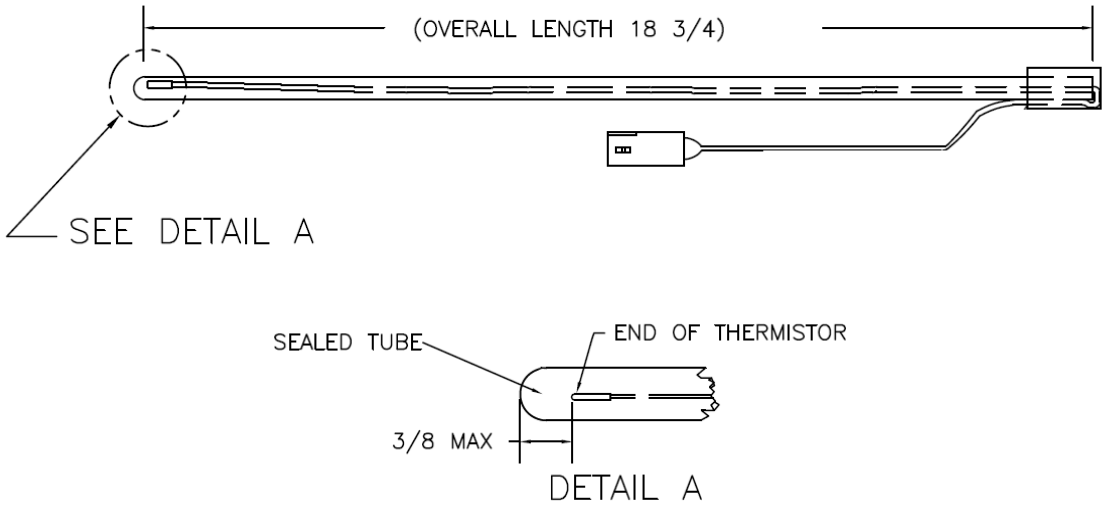

Figure 3: Structure of Subject Device

Each probe is electrically connected to a compatible reusable cable which is specified in **Table 1:** Summary of Mon-a-Therm™ 400 Series Thermistor Interface Cables and compatible monitors by the connector in the tail of the probe. The reusable cable connects the probe to a patient monitor, which is compatible with YSI-400 Series thermistor, so that the temperature measurement value is displayed on the screen of monitor. All patient monitors that meet the specifications for YSI-400 thermistor, temperature accuracy, and compatible interface cables are compatible. Refer to **Figure 4:** Illustration of Patient Monitor Compatibility.

Table 1: Summary of Mon-a-Therm™ 400 Series Thermistor Interface Cables and compatible monitors

Product Code	Cable Length	Monitor Compatibility	Monitor Connector
502-0400A	16 feet/4.87m	Most patient monitors using series 400 thermistor sensors, such as Mindray Passport2™* Monitor	 1/4 inch, right angle phono plug
502-0410A	10 feet/3.05m		
502-0405A	16 feet/4.87m	Siemens Monitor series SC	 7 pin connector
502-0415A	10 feet/3.05m		
502-0401A	16 feet/4.87m	HP or Philips Monitors such as Philips Intellivue™* Monitor	 2 pin connector
502-0411A	10 feet/3.05m		

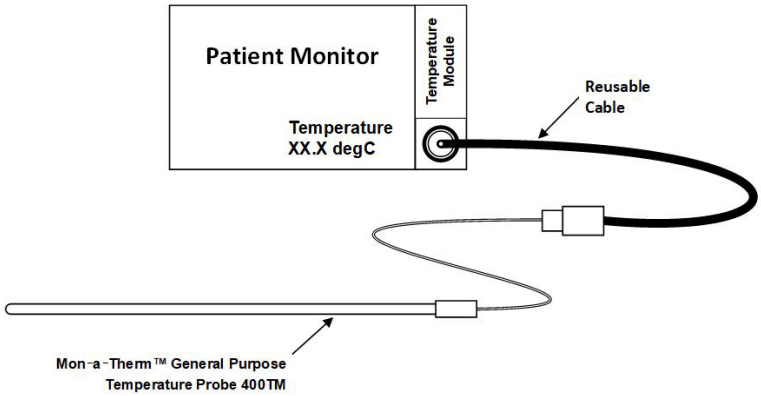

Figure 4: Illustration of Patient Monitor Compatibility

INDICATIONS FOR USE

The Mon-a-Therm™ General Purpose Temperature Probe 400TM is indicated for use in the routine monitoring of temperature in an anesthetized patient. The device is intended primarily for insertion into the esophagus or rectum, although medical judgment may dictate the selection of other anatomical sites such as the nasopharynx for some patients.

Technological Characteristics

The Mon-a-Therm™ General Purpose Temperature Probe 400TM and its predicate device, utilize the same indications for use, intended purpose, target population, user base and environmental conditions. Compared to the predicate device, the subject device maintains consistency in terms of performance specifications such as measurement range, accuracy, and shelf life.

The subject and predicate device originally adhered to the EN ISO 80601-2-56:2012 standard, requiring a temperature output range of 35°C to 42°C. However, a subsequent standard revision (EN ISO 80601-2-56:2017) expanded the required range to 34°C to 42°C. The subject device meets the stringent accuracy requirements of the newer standard, maintaining a deviation of no more than ±0.2°C within the primary range and ±0.3°C in the extended range. While the predicate device complies with the older standard, the subject device has been updated to align with the latest regulations.

The subject and predicate device utilize PVC material for their tube and sleeve components, though the materials differ in composition. The predicate device employs a clear, 73 Shore A PVC material. In contrast, the subject device features a blue, opaque, semi-rigid PVC material. Notably, the subject device's PVC formulation is not made with DEHP or Phthalates and adheres to RoHS3 compliance standards.

The subject and predicate device utilize PVC material for their tube and sleeve components, though the materials differ in composition. The predicate device employs a clear, 73 Shore A PVC material. In contrast, the subject device features a blue, opaque, semi-rigid PVC material. Notably, the subject device's PVC formulation is not made with DEHP or Phthalates and adheres to RoHS3 compliance standards.

To assess the impact of PVC material used in the tube and sleeve components, temperature accuracy testing was performed on both the subject and predicate device. The results from “Verification Test Report for Temperature Accuracy and Storage Temperature” confirmed that the PVC variations do not compromise temperature accuracy.

These differences do not raise concerns regarding the safety or effectiveness of the subject device when compared to the predicate device as concluded in the Mon-a-Therm General Purpose Temperature Probe Verification and Validation Summary Test Plan and Summary report which demonstrates that these modifications do not have any adverse impact on the performance of the device. Refer to **Bench Performance Testing** in the below table.

Consequently, it can be affirmed that the Mon-a-Therm™ General Purpose Temperature Probe 400TM is substantially equivalent to the predicate, Hi-Lo Temp® General Purpose Temperature Probe.

PERFORMANCE DATA

The following performance data were provided to support the substantial equivalence determination with the predicate device.

Bench Performance Testing

The following benchtop performance testing was provided to support the substantial equivalence determination with the predicate device.

Bench Test Category	Guidance/Standard
Safety	IEC 60601-1:2005 + AMD1:2012 + AMD2:2020 & EN 60601-1:2006/A2 2021 General requirements for basic safety and essential performance
Safety and performance	ISO 80601-2-56:2017 + A1: 2018 & EN ISO 80601-2-56:2017 + A1:2020 Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
Electromagnetic Compatibility	IEC 60601-1-2:2014 + AMD1:2020 & EN 60601-1-2:2015 + A1:2021 General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.
Usability	IEC 62366-1:2015 + AMD1:2020 &EN 62366-1:2015 + A1:2020 Application of usability engineering to medical devices IEC 60601-1-6:2010 + A1:2013 + A2:2020 & EN 60601-1-6:2010 + A1:2013 + A2:2021 General requirements for basic safety and essential performance – Collateral standard: Usability.
Biocompatibility	ISO 10993-1:2018 & EN ISO 10993-1:2020 Biological evaluation of medical devices — Evaluation and testing within a risk management process. ISO 10993-23:2021 & EN ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation. Device Classification: Contact Type - Surface Medical device, Mucosal Membrane Contact Duration - Prolonged contact, 24 hrs to 30 days Target Population - Adults, Pediatric and Neonates
Sterilization	ISO 11135-1:2014 + A1:2018 & EN ISO 11135:2014 + A1:2019 Sterilization of health care products – Ethylene Oxide. EN 556-1:2001 Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices.

Animal Performance Testing

Not applicable. No animal performance testing was required to demonstrate device safety and effectiveness.

Clinical Performance Testing

Not applicable. No clinical performance testing was required to demonstrate device safety and effectiveness.

CONCLUSIONS

Results from comprehensive verification and validating testing demonstrate that the Mon-a-Therm™ General Purpose Temperature Probe 400TM and Hi-Lo Temp® General Purpose Temperature Probe are substantially equivalent with respect to material, technological and performance characteristics.