December 29, 2025

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

Re: K251025
Trade/Device Name: Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM (90041, 90042, 90043, 90049)
Regulation Number: 21 CFR 868.1920
Regulation Name: Esophageal Stethoscope With Electrical Conductors
Regulatory Class: Class II
Product Code: BZT
Dated: April 2, 2025
Received: April 2, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JAMES J. LEE -S

for Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.

Submission Number *(if known)*

K251025

Device Name

Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM (90041, 90042, 90043, 90049)

Indications for Use *(Describe)*

The Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM is indicated for use in the routine monitoring of temperature, as well as heart and respiratory sounds, in an anesthetized patient. The device is intended for insertion into the esophagus.
The intended target populations for the Mon-a-Therm™ products are pediatrics and adults.

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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Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM
510(k) Summary

This summary of 510(k) safety and effectiveness information for the Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 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:

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Date Prepared: December 22nd, 2025

Contact Person:

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DEVICE

Trade Name:	*Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM*
Common Name:	Esophageal Stethoscope with Electrical Conductors
Classification Regulation:	*868.1920*
Classification Name:	Esophageal Stethoscope with Electrical Conductors
Regulatory Class:	Class II
Product Code:	BZT
Review Panel:	Anesthesiology

PREDICATE DEVICE

Predicate Manufacturer:	Mallinckrodt Critical Care
Predicate Trade Name:	Hi-Lo Temp® Esophageal Stethoscope
Predicate 510(k):	K811862

DEVICE DESCRIPTION

The subject device of this premarket 510(k) notification is referred to as the Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM.

The legacy Esophageal Stethoscope (K811862) was originally cleared on July 10, 1981, under the name "Hi-Lo Temp® Esophageal Stethoscope with a Thermistor Sensor." It has since been renamed to "Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM."

The Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM is currently the marketed device that is undergoing a material modification to eliminate DEHP and Phthalates.

The Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM monitors temperature and heart and breath sounds.

Features and benefits:

- Soft, thin cuff
- Male Luer fitting conveniently attaches to standard acoustical earpieces
- Long lead wire keeps connector away from the surgical field
- Compatible with most multifunction patient monitors

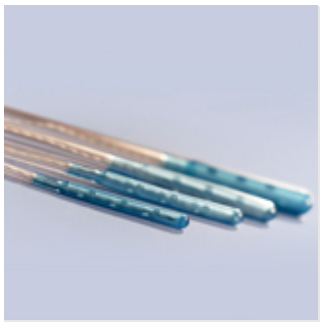

Figure 1: *Illustration of subject device Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM*

The Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM is packaged individually as a sterile, single-use device and is available in the following sizes: 12 Fr 50/case CFN 90041, 18 Fr 50/case CFN 90042, 24 Fr 50/case CFN 90043, and 9 Fr 50/case CFN 90049. 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™ Esophageal Stethoscope with Temperature Sensor 400TM components are illustrated in **Figure 2.**

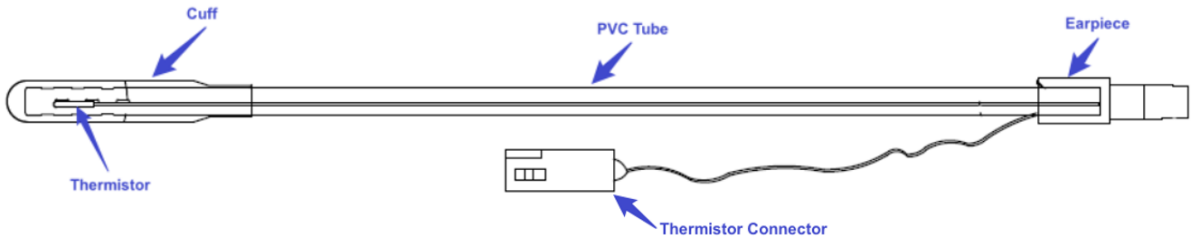

Figure 2: *Illustration of Subject Device Components*

The components of the Mon-a-Therm Esophageal Stethoscope with Temperature Sensor 400TM is illustrated in **Figure 2**. A 400 series thermistor is placed in a PVC clear tube and sealed by a blue plastisol cuff. This end of the tube is inserted into the esophagus and directly contacts mucosa. In the opposite end of the tube, there is a luer connector and a thermistor connector. The luer connector should be attached to a standard earpiece and the thermistor connector should be inserted to an appropriate interface cable.

Each probe is electrically connected to a compatible interface cable which is specified in **Table 1**. The interface cable connects the probe to a patient monitor, which is compatible with the 400 series thermistor, so that the temperature measurement value is displayed on the screen of the monitor. All patient monitors that meet the specifications for the 400 series thermistor, temperature accuracy, and compatible interface cables are compatible. Refer to **Figure 3:** 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		

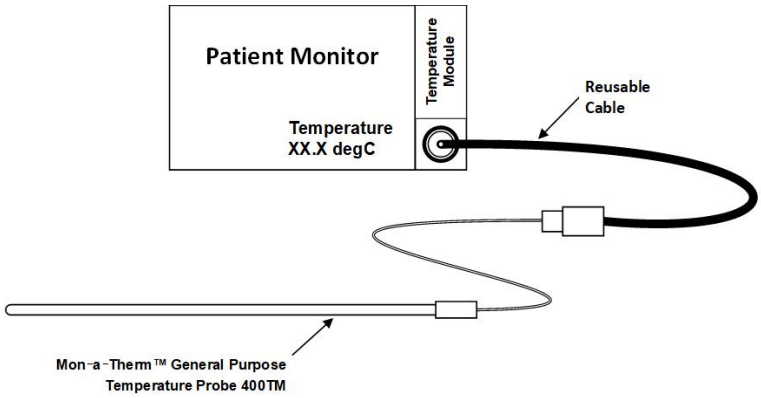

Figure 3: *Illustration of Patient Monitor Compatibility*

INDICATIONS FOR USE

The Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM is indicated for use in the routine monitoring of temperature, as well as heart and respiratory sounds, in an anesthetized patient. The devices are intended for insertion into the esophagus.

Target Patient Population

The intended target populations for the Mon-a-Therm™ products are pediatrics and adults.

TECHNOLOGICAL CHARACTERISTICS

The subject device Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM is a modification of the predicate device Hi-Lo Temp® Esophageal Stethoscope with Temperature Sensor. Both devices are equivalent in terms of intended purpose, indications for use, intended user, intended target population (with the exception of neonates), environment of use, level of invasiveness, skin contact, duration of use, sterility, and contraindications. Although both devices share the same intended use and other key characteristics, there are some material differences. The subject device uses DEHP-Free PVC in the cuff, tube and earpiece components of the device. These material differences do not raise concerns regarding the safety or effectiveness or adversely affect performance of the subject device when compared to the predicate device as demonstrated by verification and validation testing. Therefore, it has been demonstrated that the Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM is substantially equivalent to the predicate device.

PERFORMANCE DATA

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

Bench Performance Testing

Performance testing has been conducted to verify that the subject device performs as intended. Testing was carried out according to the recognized consensus standard (ISO 80601-2-56:2017+A1:2018 and IEC 60601-1:2005/AMD2:2020), as well as internally developed test

methods and acceptance criteria, to support substantial equivalence of the subject device to the predicate device. The subject device has successfully met all required standard testing in accordance with ISO 80601-2-56:2017+A1:2018 and IEC 60601-1:2005/AMD2:2020, including temperature accuracy and time response, leakage current, dielectric strength, and excessive temperature testing.

In addition to above testing, internally developed test methods were performed on terminally sterilized samples which met all defined acceptance criteria. The subject device packaging provides adequate protection by maintaining sterile integrity of the sterile barrier system (SBS) through the possible effects of aging and environmental conditions. The stability and shelf-life testing demonstrate that the subject devices maintain their intended functionality and packaging sterile barrier integrity, meeting all required standards for a 5-year shelf life.

Biocompatibility Testing

Based on the intended use and patient contact/duration of the Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM categorization, the following testing is applicable per ISO 10993-1 and FDA Use of International Standard ISO 10993-1, “Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process.”

- ☒ Cytotoxicity
- ☒ Sensitization
- ☒ Irritation/intracutaneous reactivity
- ☒ Acute systemic toxicity
- ☒ Subacute/Subchronic systemic toxicity
- ☒ Material-mediated pyrogenicity
- ☒ Implantation
- ☒ Chemical Characterization

Human Factors Evaluation

A Human Factors assessment was conducted and the Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM was found to be in conformance with EN 62366-1:2015+A1:2020 and IEC 62366-1:2015+A1:2020.

Sterilization

The subject devices are sterilized by ethylene oxide (EO) sterilization method. They are not intended to be reprocessed or sterilized by the end user. The EO sterilization effectively sterilizes the subject devices to a sterility assurance level (SAL) of 10^{-6}.

Animal Performance Testing

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

Clinical Performance Testing

Not Applicable. No clinical data were necessary to demonstrate device safety and effectiveness.

CONCLUSIONS

The Mon-a-Therm™ Esophageal Stethoscope with Temperature Sensor 400TM and Hi-Lo Temp® Esophageal Stethoscope with Thermistor Sensor are equivalent in terms of intended purpose, indications for use, intended user, intended target population (with the exception of neonates), environment of use, level of invasiveness, skin contact, duration of use, sterility, and contraindications. Results from comprehensive verification and validation testing demonstrate that both the subject and predicate device are substantially equivalent with respect to material, technological and performance characteristics.