September 20, 2021

Medline Industries, Inc.
Kelsey Closen
Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K211931
Trade/Device Name: Medline Digital Thermometer Non-Lubricated Probe Sheath
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 15, 2021
Received: June 22, 2021

Dear Kelsey Closen:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For Payal Patel
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211931

Device Name

Medline Digital Thermometer Non-Lubricated Probe Sheath

Indications for Use *(Describe)*

These devices are indicated for use as a barrier accessory to digital thermometers while taking rectal, oral or axillary temperature measurements. These sheaths are non-sterile and intended for single use only. This accessory is contraindicated for use with broken skin.

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 K211931

[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Contact Person
Contact Person: Kelsey Closen, Regulatory Affairs Specialist
Phone: 847-949-2283
Email: KClosen@medline.com

Summary Preparation Date
September 20, 2021

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline Digital Thermometer Non-Lubricated Probe Sheath
Common Name: Clinical Electronic Thermometer
Regulation Name: Clinical electronic thermometer
Product Code: FLL
Classification Panel: General Hospital
Regulatory Class: II
Regulation Number: 21 CFR 880.2910

Predicate Device
Medline Digital Rectal Thermometer Sheath, K183431

Device Description
The Medline Digital Thermometer Non-Lubricated Probe Sheath is an accessory to a clinical electronic thermometer, which is intended to measure body temperature. The Medline Digital Thermometer Non-Lubricated Probe Sheath is a flexible plastic sheath that is used to cover the transducer of clinical electronic thermometers while taking body temperature measurements from the oral, axillary, or rectal measurement sites and acts as a barrier to prevent possible contamination of the device during

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temperature measurement. The sheath is an over-the-counter (OTC), disposable, single use, non-lubricated, and non-sterile device that is compatible with most digital stick thermometers.

Indications for Use

These devices are indicated for use as a barrier accessory to digital thermometers while taking rectal, oral or axillary temperature measurements. These sheaths are non-sterile and intended for single use only. This accessory is contraindicated for use with broken skin.

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Digital Thermometer Non-Lubricated Probe Sheath	Medline Digital Rectal Thermometer Sheath	N/A
510(k) Reference	TBD	K183431	N/A
Product Owner	Medline Industries, Inc.	Medline Industries, Inc.	Same
Indications for Use	These devices are indicated for use as a barrier accessory to digital thermometers while taking rectal, oral or axillary temperature measurements. These sheaths are non-sterile and intended for single use only. This accessory is contraindicated for use with broken skin.	These devices are indicated for use as a barrier accessory to digital thermometers while taking rectal temperature measurements. These sheaths are nonsterile and intended for single use only. This accessory is contraindicated for use with broken skin.	Different
Design Standard	Conforms to Standard ASTM E1104-98	Conforms to Standard ASTM E1104-98	Same
Design Features & Configurations	One size, Clear, Flexible, peel- away package, marking for device insertion	One size, Clear, Flexible, peel-away package, marking for device insertion	Same
Prescription vs. OTC	OTC	OTC	Same
Application Site	Oral, axillary, rectal	Rectal	Different

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Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Single Use vs. Reusable	Single Use	Single Use	Same

Discussion

The application site is different between the proposed device and the predicate. Biocompatibility was conducted per ISO 10993, *"Biological Evaluation of the Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process*." to address this difference.

Summary of Non-Clinical Testing

Testing was conducted to demonstrate safety and effectiveness of the Medline Digital Thermometer Non-Lubricated Probe Sheath. A summary of testing is presented below with more information provided in the applicable sections.

Biocompatibility Testing

The biological evaluation for the Medline Digital Thermometer Non-Lubricated Probe Sheath was conducted in accordance with FDA guidance document, "*Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* and ISO 10993-1 *"Biological Evaluation of the Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process*."

The following Biocompatibility tests were performed:

- ISO 10993-5: Cytotoxicity
- ISO 10993-10: 2010: Skin Sensitization
- ISO 10993-10: 2010: Skin Irritation

Performance Testing (Bench)

Performance testing on the Medline Digital Thermometer Non-Lubricated Probe Sheath was conducted for compatibility and leakage per the *ASTM E1104-98 (2016): Standard Specification for Clinical Thermometer Probe Covers and Sheaths* and tensile strength.

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TABLE 2: Performance Testing

Test	Testing Standards	Acceptance Criteria
Compatibility	ASTM E1104-98(2016) 5.4	Probe cover shall not degrade the measurement time or accuracy of the temperature-taking device such that the probe and temperature-taking unit fails to meet the requirements of ASTM E1112 – § 4.2
Leakage	ASTM E1104-98 (2016) 5.3	There shall be no continuous bubble stream observed from the probe cover within 5 seconds of applying an internal pressure of 8.4 kPa.

Summary of Clinical Testing

Not applicable.

Conclusion

The differences between the predicate and the subject device do not raise and new or different questions of safety or effectiveness. Medline Industries, Inc. concludes that the Medline Digital Thermometer Non-Lubricated Probe Sheath are substantially equivalent to the predicate device Medline Digital Rectal Thermometer Sheath cleared under K183431.