June 14, 2019

Medline Industries, Inc.
Dinah Rincones
Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K183431
Trade/Device Name: Medline Digital Rectal Thermometer Sheath
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: May 14, 2019
Received: May 16, 2019

Dear Dinah Rincones:

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 Tina Kiang, Ph.D
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183431

Device Name
Medline Digital Rectal Thermometer Sheath

Indications for Use *(Describe)*
These devices are indicated for use as a barrier accessory to digital thermometers while taking rectal 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.

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Section 5: 510(k) Summary

5.1. 510(k) Device Identification

DATE OF PREPARATION:	June 14, 2019
SPONSOR/SUBMITTER:	Medline Industries, Inc. Three Lakes Drive Northfield, IL 60093 Registration Number: 1417592
CONTACT:	Dinah Rincones Regulatory Affairs Specialist
TELEPHONE	847-949-2687
FAX:	224-931-1271
EMAIL:	DRincones@medline.com
DEVICE TRADE NAME:	Medline Digital Rectal Thermometer Sheath
COMMON NAME:	Digital Thermometer Sheaths
CLASSIFICATION NAME:	Clinical Electronic Thermometer
REGULATION NUMBER:	21 CFR §880.2910
PRODUCT CODE:	FLL
DEVICE CLASS:	Class II
PREDICATE DEVICE:	SaniTherm Thermometer Sheaths, Oral and Rectal, Digital and Mercury, K983406

5.2. Device Description

The Medline Digital Rectal Thermometer Sheath is an accessory to a clinical electronic (digital) thermometer, a Class II device in the US, intended to measure the body temperature of a patient by means of a transducer coupled with an electronic signal amplification, conditioning and display unit. The sheath covers the transducer and is a single-use disposable device. Digital Thermometer Sheaths may not be suitable for clinical thermometers which employ rigid plastic sheaths.

Products offered: Medline Digital Rectal Thermometer Sheaths (Only one model number is being offered).

5.2.1. Device Format

The Medline Digital Rectal Thermometer Sheath is offered over the counter, with 100 sheaths per carton. This accessory to digital rectal thermometers are sold non-sterile.

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5.3. Indications for Use Statement

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

5.4. Subject Device vs. Predicate Device (Substantial Equivalence)

The Medline Digital Rectal Thermometer Sheaths are substantially equivalent to the predicate SaniTherm Thermometer Sheaths, Oral and Rectal, Digital and Mercury, K983406. The comparison of the characteristics are summarized below.

Comparison of Technological Characteristics with the Predicate Device

Feature		**Medline Digital Rectal Thermometer Sheath**	**Predicate**	**Comparison Analysis**
			SaniTherm Thermometer Sheaths, Oral and Rectal, Digital and Mercury	N/A
510(k) Number		K183431	K983406	N/A
Indication for Use		These devices are indicated for use as a barrier accessory to digital thermometers while taking rectal 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 that is used as an accessory to oral or rectal, digital or mercury thermometers. These sheaths are non-sterile and are intended for single patient use only.	Different
Design:		The Medline Digital Rectal Thermometer Sheath is an accessory to a clinical electronic (digital) thermometer. The sheath covers the clinical electronic thermometer transducer and is a single-use disposable device. Medline Digital Rectal Thermometer Sheaths may not be suitable for clinical thermometers which employ rigid plastic sheaths. The device is not made of natural rubber latex.	SaniTherm Disposable Thermometer Sheaths are plastic coverings used for either oral or rectal, mercury or digital thermometers. Digital Thermometer Sheaths may not be suitable for use with all clinical thermometers. Example - Clinical thermometers which employ rigid plastic sheaths.	Different
Construction		PP Plastic Film with upper and Lower exterior protective plastic	PP Plastic Film with upper and Lower exterior protective plastic	Same
Use Type		For Single Use	For Single Use	Same
Packaging		Non-Sterile Package	Non-Sterile Package	Same
Outside Dimension	Length	119 mm ± 0.0	122.3 ± 0.6	Different
	Width	29 mm ± 0.0	28.3 ± 0.6	Different

	Radius	3 ±0.0	2 ± 0.0	Different
	Base-Tip	29 mm	30 ± 1.7	Different
Materials in skin contact:		Protective Film: ethylene methyl acrylate copolymer film	Protective Film: ethylene methyl acrylate copolymer film	Same
		Lubricant: Lubrajel MG	Lubricant: Lubrajel MG	Same
Biocompatibility		Biocompatibility testing according to ISO 10993-5 & 10 • Cytotoxicity • Sensitization • Irritation	Biocompatibility testing according to ISO 10993-5 & 10 • Cytotoxicity • Sensitization • Irritation	Same
Strength		Performance test according to ASTM E1104:98 (2016).	Performance test according to ASTM E1104:98 (2016).	Same
Accuracy		Performance test according to ASTM E1104:98 §5.4 (2016)	Performance test according to ASTM E1104:98 §5.4 (2016)	Same

Discussion of differences: Both the subject device and predicate device have similar intended use, same materials and structures. The difference in the dimensions do not raise new or different questions of safety or effectiveness. In addition, the difference in the indications for use for the subject device to be used for rectal temperature readings only does not raise new or different questions because the predicate device is also used for rectal temperature readings and oral temperature readings.

5.5. Performance Summary

5.5.1.1. Biocompatibility

Biocompatibility in accordance with appropriate sections of ISO 10993-5 and ISO 10993-10 evaluated all materials used in the Medline Digital Rectal Thermometer Sheaths for:

- Cytotoxicity
- Sensitization
- Irritation

5.5.2. Performance Study

Material strength and temperature compatibility of the Medline Digital Rectal Thermometer Sheaths were tested per ASTM E1104:98 (2016) and compared with the predicate device. Sheath material strength and accuracy met acceptance criteria. The medical grade lubricant used for the thermometer sheaths met the acceptance criteria for lubricity (coefficient of friction).

Test	Test Method	Results
Strength	ASTM E1104:98 (2016)	Testing for tensile strength and lubricity (coefficient of friction) of

Test	Test Method	Results
		the lubricated sheath met acceptance criteria.
Accuracy	ASTM E1104:98 (2016)	Testing showed that the sheath and lubricant materials met acceptance criteria.

5.6. Conclusion

The Medline Digital Rectal Thermometer Sheath has similar intended use, materials and characteristics as the predicate device. Performance testing demonstrated that the subject device is shown to be substantially equivalent to the predicate device, SaniTherm Thermometer Sheaths, Oral and Rectal, Digital and Mercury, K983406.

There are no new or different questions of safety and effectiveness of the Medline Digital Rectal Thermometer Sheath when compared to the predicate device.