January 17, 2018

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

Re: K173113
Trade/Device Name: Medline Disposable Electronic Thermometer Probe Cover
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 15, 2017
Received: December 18, 2017

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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

510(k) Number *(if known)*

K173113

Device Name
Medline Disposable Electronic Thermometer Probe Cover

Indications for Use *(Describe)*

The Medline Disposable Electronic Thermometer Probe Covers are intended for use as barriers between any SureTemp and SureTemp Plus digital thermometer probe and users' oral, rectal, or axillary measuring sites to avoid possible contamination and infection during temperature measuring. The probe covers are non-sterile and intended for single use only.

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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K173113

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

Submitter / 510(k) Sponsor
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093
Registration Number: 1417592

Contact Person
Dinah Rincones
Regulatory Specialist
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Summary Preparation Date
September 28, 2017

Type of 510(k) Submission
Traditional

Device Name / Classification
Name of Device: Clinical Electronic Thermometer Probe Cover
Proprietary Name: Medline Disposable Electronic Thermometer Probe Cover
Common Name: Clinical Electronic Thermometer Probe Cover
Product Code: FLL
Classification Panel: General Hospital
Device Class: Class II
Regulation #: 21 CFR 880.2910

Predicate Device
The *Welch Allyn SureTemp Plus Thermometer (K030580)* is identified herein as the predicate device of the Medline Disposable Electronic Thermometer Probe Cover.

Please note that the primary predicate 510(k) to support this submission, K030580, included both the thermometer probe cover, as well as the SureTemp Plus thermometer itself. However, only the thermometer probe cover is included within the scope of this premarket notification; Medline does not

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intend to market any other component or accessory of the SureTemp Plus thermometer system, nor the thermometer itself.

Device Description

The proposed device is a disposable, single use, non-sterile shell-like device used to cover electronic thermometer probes of temperature taking devices. The Medline Disposable Electronic Thermometer Probe Cover is compatible with the intended use of all SureTemp and SureTemp Plus reusable digital thermometers probes, which require the use of probe covers for oral, axillary, or rectal temperature measurements.

Indications for Use

The Medline Disposable Electronic Thermometer Probe Covers are intended for use as barriers between any SureTemp and SureTemp Plus digital thermometer probe and users' oral, rectal, or axillary measuring sites to avoid possible contamination and infection during temperature measuring. The probe covers are non-sterile and intended for single use only.

Summary of Technological Characteristics

The Medline Disposable Electronic Thermometer Probe Cover is similar in design, intended use and function to the thermometer probe cover cleared under K030580.

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	The Medline Disposable Electronic Thermometer Probe Covers	The Welch Allyn SureTemp Plus Thermometer	**N/A**
510(k) Reference	TBD	K030580	**N/A**
Product Owner	Medline Industries, Inc.	Welch Allyn Inc.	**N/A**
Product Code	FLL	FLL	**Same**
Intended Use	The Medline Disposable Electronic Thermometer Probe Covers are intended for use as barriers between any SureTemp and SureTemp Plus digital thermometer probe and users' oral, rectal, or axillary measuring sites to avoid the possible contamination and infection during temperature measuring. The probe covers are non-sterile and intended	Electronic Thermometer: The Welch Allyn SureTemp Plus thermometer enables the health care professional to make an accurate prediction of oral, rectal or axillary temperature. Electronic Thermometer Probe Cover: Probe covers are intended to cover the thermometer probe prior to its use. This cover must not be a significant barrier to the transfer of heat from the	**Same*** *The predicate's thermometer probe covers are accessories to the thermometer itself, and were included in its 510(k) clearance under K030580. Only the probe covers are included in this 510(k), as Medline does not

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	for single use only.	patient to the probe body (and thermistor). In addition, the disposable nature of the probe cover prevents microbiological cross-contamination among patients which might occur with a reusable probe.	intend to market any other component or accessory of the SureTemp Plus thermometer system, nor the thermometer itself. The proposed device's Indications for Use are, therefore, more narrow than the Indications for Use stated in K030580, which applied to both the thermometer and the probe covers, as the proposed device's indications are only applicable to the probe covers.
Regulation Number	21 CFR 880.2910	21 CFR 880.2910	**Same**
Design Features	Conforms to ASTM Standard E1104	Conforms to ASTM Standard E1104	**Same**
Design Configurations	One size	One size	**Same**
Performance Specifications	Conforms to ASTM Standard E1104	Conforms to ASTM Standard E1104	**Same**
Prescription vs. OTC	Prescription Only	Prescription Only	**Same**
Sterile vs. Non-Sterile	Non-sterile	Non-sterile	**Same**
Disposable vs. Non-Disposable	Disposable	Disposable	**Same**
Single Use vs. Reusable	Single Use Only	Single Use Only	**Same**

Summary of Non-Clinical Testing

Non-clinical verification of the Medline Disposable Electronic Thermometer Probe Cover has been conducted to evaluate its performance and functionality. The results of these tests have demonstrated the overall performance of the proposed device and ultimately support a substantial equivalence determination.

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Specifically, the evaluation of the proposed device includes:

- Performance Testing (Bench)
  - In accordance with ASTM E1104-98 (2016)
- Biocompatibility Testing
  - ISO 10993-5: Cytotoxicity – MEM Elution;
  - ISO 10993-10: Irritation – Intracutaneous reactivity; and,
  - ISO 10993-10: Delayed-Type Hypersensitivity (Sensitization) – Guinea Pig Maximization Test.

Conclusion

In accordance with 21 CFR Part 807, and based on a comparison of 'Indications for Use,' technological characteristics and performance data, Medline Industries, Inc. concludes that the proposed Medline Thermometer Probe Cover is substantially equivalent to the predicate device cleared under K030580.