September 20, 2018

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

Re: K181726
Trade/Device Name: Medline Patient Cables and Lead Wires
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: July 20, 2018
Received: July 23, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Jessica E. Paulsen -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K181726

Device Name
Medline Patient Cables and Lead Wires

Indications for Use *(Describe)*
Medline Patient Cables and Lead Wires are used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional. Additionally, the use of Medline Patient Cables and Lead Wires is limited by the indications for use of the ECG monitoring or diagnostic equipment it is connected to. Medline Patient Cables and Lead Wires are intended for Prescription 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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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 Affairs Specialist
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Summary Preparation Date
June 28, 2018

Type of 510(k) Submission
Traditional

Device Name / Classification
- Device Common Name – Patient transducer and cable
- Proprietary Name – Medline Patient Cables and Lead Wires
- Device Class - II
- Panel – Cardiovascular
- Product Code – DSA
- Regulation Number – 21 CFR §870.2900

Predicate Device
The legally-marketed predicate device that is most suitable for comparison with Medline Patient Cables and Lead Wires is: *Curbell Patient Monitoring Cables and Lead Wires.* This device was cleared under 510(k) number K081762 on August 18th, 2008 to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional.

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Subject Device Description

Medline Patient Cables and Lead Wires are used to transmit signals from patient surface electrodes to various electrocardiograph (ECG) recorders/monitors for diagnostic and/or monitoring purposes.
Medline Patient Cables and Lead Wires are not stand-alone devices, but are accessories to legally-marketed ECG monitors and patient electrodes, ultimately acting as a conduit between the two to transmit signals from the patient to the monitor.

The proposed device consists of two distinct parts – reusable trunk cables and disposable lead wires – which are used as a system to transfer signals originating from skin-mounted EGG electrodes (distal end) to an ECG monitoring device (proximal end). All designs of Medline Trunk Cables feature a monitor connector at one end, which mates with a designated OEM monitor, and a yoke connector at the other end, which provides the connection point from the trunk cable to the lead wires. Similarly, all designs of Medline Lead Wires feature a lead connector at one end, which mates with the yoke end of the trunk cable, and an electrode connector at the other end, which attaches to patient electrodes. It is this system's cabling that facilitates the conduction of signals from the electrodes to the ECG monitoring device.

Indications for Use

Medline Patient Cables and Lead Wires are used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional. Additionally, the use of Medline Patient Cables and Lead Wires is limited by the indications for use of the ECG monitoring or diagnostic equipment it is connected to.
Medline Patient Cables and Lead Wires are intended for Prescription Use only.

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Summary of Technological Characteristics

TABLE 1: COMPARISON OF SUBJECT AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device (K081762)	Comparison Analysis
PRODUCT NAME	Medline Patient Cables and Lead Wires	Curbell Patient Monitoring Cables and Lead Wires	DIFFERENT
PRODUCT CODE	DSA	DSA	SAME
CLASSIFICATION NAME	Patient Transducer and Electrode Cable (Including Connector)	Patient Transducer and Electrode Cable (Including Connector)	SAME
REGULATION NUMBER	21 CFR §870.2900	21 CFR §870.2900	SAME
DEVICE CLASS	Class II	Class II	SAME
COMMON NAME	ECG Cable and Lead Wire	ECG Cable and Lead Wire	SAME
ANATOMICAL SITES	Attached to sensors placed at specified locations as required by the patient monitor. Examples include Left arm, Right arm, Chest, Left leg & Right leg.	Attached to sensors placed at specified locations as required by the patient monitor. Examples include Left arm, Right arm, Chest, Left leg & Right leg.	SAME
INTENDED USE	Used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional.	Used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional.	SAME
PRINCIPLE OF OPERATION	Includes trunk cables and lead wires that form a conduction channel for transmitting signals from electrodes affixed to patient skin to an ECG monitoring device. Lead wires attach to patient electrodes at one end and to a corresponding trunk cable at the other end. Trunk cables then span from lead wire connection point at this end, to their opposite end that plugs into a respective ECG monitor, facilitating signal conduction from patient to monitor. Use and function of this device is limited to the area spanning from the patient electrodes to the	Includes trunk cables and lead wires that form a conduction channel for transmitting signals from electrodes affixed to patient skin to an ECG monitoring device. Lead wires attach to patient electrodes at one end and to a corresponding trunk cable at the other end. Trunk cables then span from lead wire connection point at this end, to their opposite end that plugs into a respective ECG monitor, facilitating signal conduction from patient to monitor. Use and function of this device is limited to the area spanning from the patient electrodes to the ECG monitoring device, where it provides a means of cable	SAME

Device Characteristic	Proposed Device	Predicate Device (K081762)	Comparison Analysis
	ECG monitoring device, where it provides a means of cable connection for the transmission of signals.	connection for the transmission of signals.	
APPEARANCE	Designed as replacements for similar cables manufactured by the Original Equipment Manufacturers (OEM) and other third party manufacturers for their respective ECG monitors. Include Trunk Cables and Lead Wires with various type of connectors at each end (monitor, trunk/lead wire, electrode pinch or snap)	Designed as replacements for similar cables manufactured by the Original Equipment Manufacturers (OEM) and other third party manufacturers for their respective ECG monitors. Include Trunk Cables and Lead Wires with various type of connectors at each end (monitor, trunk/lead wire, electrode pinch, snap or Sure Lock)	SIMILAR
LEAD WIRE CONSTRUCTION	Shielded Copper with polyurethane jacket	Shielded and Unshielded Copper with polyurethane jacket	SIMILAR
TRUNK CABLES LENGTH	2500mm	3848mm	SIMILAR
LEAD WIRES LENGTH	965mm	457mm to 1311mm	SIMILAR
NUMBER OF LEADS	3 and 5 lead versions	3, 5 and 6 lead versions	SIMILAR
TYPE OF USE (RX VS OTC)	Prescription Use	Prescription Use	SAME
USE ENVIRONMENT	Health Care Settings	Health Care Settings	SAME
STERILITY	Non-Sterile	Non-Sterile	SAME
TRUNK CABLES USAGE	Reusable	Reusable	SAME
LEAD WIRES USAGE	Disposable (Single Use)	Reusable	DIFFERENT

Summary of Non-Clinical Testing

Biocompatibility Testing

The biological evaluation for the Medline Patient Cables and Lead Wires 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 proposed device (Medline Lead Wire Models only) is in direct contact with the skin for a prolonged duration of contact (> 24 hours to 30 days); therefore, the following biocompatibility tests were performed:

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- Cytotoxicity – MEM Elution per ISO 10993-5: 2009 “Biological Evaluation of Medical Devices- Part 5: Tests for *in vitro* cytotoxicity.”
- Buehler Dermal Sensitization – Repeated Patch (GLP-2 Extracts) per ISO 10993-10: 2010 “Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization.”
- Irritation – Primary Skin Irritation per ISO 10993-10: 2010 “Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization.”

Performance Testing

Functional performance testing was conducted to demonstrate that the proposed device meets the standard specifications for a Patient Transducer and Electrode cable (including connector). To assure this, the Medline Patient Cables and Lead Wires were tested in accordance with the following standards applicable to this device type:

- IEC 60601-1:2005 (Third Edition) + CORR, 1:2006 + CORR. 2:2007 + A1:2012 – “Medical electrical equipment – Part 1: General requirements for basic safety and essential performance”.
- IEC 60601-2-27:2011 – “Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.
- ANSI/AAMI EC53:2013 – “ECG trunk cables and patient lead wires”

Summary of Clinical Testing

Not applicable.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline Patients Cables and Lead Wires are as safe and as effective for their intended use as the predicate device Curbell Patient Monitoring Cables and Lead Wires (K081762).