December 3, 2021

Medline Industries, Inc.
Claire Pigman
Sr. Manager, Regulatory Affairs
Three Lakes Drive
Northfield, Illinois 60093

Re: K212258
Trade/Device Name: Medline Cardiovascular Procedure Kit
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: Class II
Product Code: LRO
Dated: September 13, 2021
Received: September 15, 2021

Dear Claire Pigman:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K212258

Device Name
Medline Cardiovascular Procedure Kit

Indications for Use *(Describe)*
The Medline Cardiovascular Procedure Kit contains a single-use sterile surgical drape intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The drape is packaged and sterilized with disposable devices intended for professional use/used by licensed physicians in preparing the operating environment for, and performing cardiovascular procedures and surgeries. The intended use of the medical products assembled in these kits will not be changed from the manufacturer's original intended use.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**Medline Industries, Inc.**
Three Lakes Drive
Northfield, IL 60093

# 510(k) SUMMARY
**[AS REQUIRED BY 21 CFR 807.92]**

## SUMMARY PREPARATION DATE
November 19, 2021

## SUBMITTER / 510(k) SPONSOR
Medline Industries, Inc.
Three Lakes Drive
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Registration Number: 1417592

## SUBMISSION CORRESPONDENTS
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## TYPE OF SUBMISSION
Traditional 510(k)

## DEVICE NAME / CLASSIFICATION
Trade Name: Medline Cardiovascular Procedure Kits
Common Name: Cardiovascular Procedure Kit
Classification Name: General Surgery Tray
Product Code: LRO
Classification Panel: General & Plastic Surgery
Regulatory Class: Class II
Regulation Number: 21 CFR 878.4370

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## PREDICATE DEVICES

K962826 – Medline Radiology-Diagnostic Kits

## INDICATIONS FOR USE

The Medline Cardiovascular Procedure Kit contains a single-use sterile surgical drape intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The drape is packaged and sterilized with disposable devices intended for professional use/used by licensed physicians in preparing the operating environment for, and performing cardiovascular procedures and surgeries. The intended use of the medical products assembled in these kits will not be changed from the manufacturer's original intended use.

## DEVICE DESCRIPTION

The Medline Cardiovascular Procedure Kit is customized to meet requirements of the hospitals and health care professionals utilizing them. The kit is provided sterile, single-use and includes a range of components dependent upon the specific procedure. These kits are assembled for customer convenience using Medline and other manufacturer's currently manufactured/marketed components. Customers specify the kit contents, quantity, and placement of individual components in the kit. A component listing is provided within this submission, which includes the name and regulatory status of components that can be selected for placement in various configurations of the final Medline Cardiovascular Procedure Kits. The BOM provides the corresponding FDA product codes, and reference to respective marketing clearances (as applicable). These included components are standard for cardiovascular procedures.

The intended use of the products assembled in the final Medline Cardiovascular Procedure Kit will not be changed. These components are all legally marketed drug products, and/or medical devices that are either: (1) pre-amendment devices; (2) 510(k)-cleared devices; or (3) 510(k) exempt devices. Commodity products, not regulated by FDA, are additionally included in the proposed kit. The customer may also specify a certain brand of similar items or minor variations of items. If additional components and/or manufacturers must be added to this list, we certify the regulatory compliance of the added components and maintain the information in our internal Device Master Record.

## SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Medline Cardiovascular Procedure Kit containing single-use sterile surgical drapes, has the same intended use and utilizes similar components, assembly practices, component sourcing evaluation procedures, and sterilization processes as the predicate. The predicate device, K962826 – Medline Radiology-Diagnostic Kit, was cleared as a convenience kit similar in nature to the proposed device.
K962826 is similarly classified under product code LRO and contains surgical drapes assembled for customer convenience with currently manufactured components based on the customer's specifications (i.e. placement of items in the kit, item quantities, and specific brand of similar components or variation of components). The intended use and design of components assembled in the subject and predicate kits are not altered in any way.

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## SUMMARY OF NON-CLINICAL TESTING

The safety and performance evaluation of the subject Medline Cardiovascular Procedure Kit was conducted based upon a risk assessment and evaluated in accordance with applicable recognized standards and FDA guidance documents, including:

- ISO 10993-1 *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*
- AAMI/ANSI/ISO 10993-7, *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals*.
- FDA's Convenience Kits, Interim Regulatory Guidance: 20 May 1997
- FDA's Sterilized Convenience Kits for Clinical and Surgical Use: 7 January 2002

## STERILIZATION

The Medline Cardiovascular Procedure Kit is terminally sterilized by ethylene oxide (EO) to deliver a minimum sterility assurance level of $10^{-6}$. Medline ensures sterility of the components in the final Medline Cardiovascular Procedure Kit, and that the sterilization process does not adversely or unintentionally impact the materials that would affect the functionality of the kit components.

## SUMMARY OF CLINICAL TESTING

Not applicable.

## SUMMARY OF ANIMAL TESTING

Not applicable.

## 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 Cardiovascular Procedure Kit is substantially equivalent to the predicate devices.