October 24, 2025

Medline Industries, LP.
Susan Carlson
Senior Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K250345
Trade/Device Name: Medline Bag Decanter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: LHI
Dated: September 26, 2025
Received: September 26, 2025

Dear Susan Carlson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

DAVID WOLLOSCHECK
-S

David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250345

Device Name
Medline Bag Decanter

Indications for Use *(Describe)*
Intended for the aseptic dispensing of solutions from IV containers. For use in transferring IV fluids/medication from a bag to an IV fluid administration device.

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.

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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."

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

Submitter / 510(k) Sponsor
Applicant Name: Medline Industries, LP
Applicant Address: Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Submission Correspondent
Contact Name: Susan Carlson
Senior Regulatory Affairs Specialist
Contact Email: scarlson@medline.com
Contact Phone: (847) 247-7531

Summary Preparation Date
October 23, 2025

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline Bag Decanter
Common Name: Decanting Device
Classification Name: Set, I.V. Fluid Transfer
Product Code: LHI
Classification Panel: General Hospital & Personal Use
Regulatory Class: Class II
Regulation Number: 21 CFR 880.5440

Predicate Device
Submission Number: K182819
Trade Name: GCMEDICA Bag Transfer Device

Device Description
The Medline Bag Decanter is a non-pyrogenic, single use, disposable device, which is supplied sterile. The device comprises of a one-piece transfer device with protective flexible caps at either end. The device is an injection molded hollow tube with a spiked end used to access the source container and withdraw fluid. The spike component is designed with a built-in splash guard. The device is designed for use in transferring IV fluids/medication from a bag to an IV fluid administration device.

Indications for Use

Intended for the aseptic dispensing of solutions from IV containers. For use in transferring IV fluids/medication from a bag to an IV fluid administration device.

Summary of Technological Characteristics

The proposed device, Medline Bag Decanter (K250345), and the predicate device, GCMEDICA Bag Transfer Device (K182819), are substantially equivalent, as evaluated in the table below.

TABLE 1: COMPARISON OF PROPOSED DEVICE AND PREDICATE DEVICE.

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Bag Decanter	GCMEDICA Bag Transfer Device	**N/A**
510(k) Reference	K250345	K182819	**N/A**
Product Owner	Medline Industries, LP.	GCMedica Enterprise, LTD. (WUXI)	**N/A**
Product Code	LHI	LHI	**Same**
Regulation Number	880.5440	880.5440	**Same**
Classification Name	Set, I.V. Fluid Transfer	Set, I.V. Fluid Transfer	**Same**
Classification Panel	General Hospital & Personal Use	General Hospital & Personal Use	**Same**
Intended Use / Indications for Use	Intended for the aseptic dispensing of solutions from IV containers. For use in transferring IV fluids/medication from a bag to an IV fluid administration device.	Intended for the aseptic dispensing of solutions from IV containers. For use in transferring IV fluids/medication from a bag to an IV fluid administration device.	**Same**
Design Features	Proposed Device Model consists of an injection molded hollow tube/spout, spiked end, protective caps, and built-in splash guard. 	Predicate Device Model consists of spike, protective caps, hollow tubing/spout, and a splash guard. 	**Same**
Design Configurations	Length: 9-inch	Length: 9-inch	**Same**
Materials	Body: ABS Caps: PE	Body: ABS Caps: PE	**Same**
Prescription vs. OTC	Prescription Use	Prescription Use	**Same**

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Contact Durations	Externally communicating device intended for indirect blood path contact for a limited contact duration (< 24 hours)	Externally communicating device intended for indirect blood path contact for a limited contact duration (< 24 hours)	**Same**
Sterile vs. Non-Sterile	Sterile	Sterile	**Same**
Disposable vs. Non-Disposable	Disposable	Disposable	**Same**
Single Use vs. Reusable	Single Use	Single Use	**Same**

As evidenced by the comparison table above, the proposed device, Medline Bag Decanter (K250345), and the predicate device, GCMEDICA Bag Transfer Device (K182819), have the same characteristics, including intended use, technological characteristics, principles of operation, and design features.

Summary of Non-Clinical Testing

Testing was conducted to demonstrate substantial equivalence between the proposed device, Medline Bag Decanter (K250345) and the predicate device, GCMEDICA Bag Transfer Device (K182819).

Biocompatibility Testing

The biological evaluation for the proposed device, Medline Bag Decanter (K250345), 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 10993-1:2018, *Biological Evaluation of the Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process.*

In accordance with ISO 10993-1, the materials of the Medline Bag Decanter are characterized as an externally communicating device intended for indirect blood path contact for a limited duration (< 24 hours), as such the following biological endpoints were evaluated in the biological evaluation report:

- Physical and Chemical Information
- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemocompatibility

Performance Testing (Bench)

The following functional performance tests were conducted on the proposed device, Medline Bag Decanter (K250345) to ensure that the device meets the standard specifications for fluid decanters in accordance with applicable requirements outlined in FDA guidance document entitled *"Guidance for Industry and FDA Review Staff - Intravascular Administration Sets Premarket Notification Submissions [510(k)]"* and to demonstrate the safety and effectiveness the device for its intended use.

- Device Appearance/Visual Inspection
- Device Flow Rate per ISO 8536-4:2019
- Device Leakage per ISO 8536-4:2019
- Device Spike Penetration Force per ISO 8536-2:2023
- Aseptic Presentation Testing per ISO 11607-1:2019 [Including AMD1:2023]
- Chemical Testing per ISO 8536-4:2019
- Particulate Testing per ISO 8536-4:2019
- Simulated Use Testing/Design Validation
- Packaging Appearance/Visual Inspection per ASTM F1886/F1886M-16
- Packaging Blue Dye Penetration per ASTM F1929-15
- Packaging Bubble Leak Test per ASTM F2096-11 (Reapproved 2019)
- Packaging Seal Strength per ASTM F88/F88M-21

Performance Testing (Animal)

This section does not apply. No animal testing was performed.

Performance Testing (Clinical)

This section does not apply. No clinical testing was performed.

Conclusion

Based on the information provided in this premarket notification and in accordance with 21 CFR Part 807, Medline Industries, LP. concludes that the proposed device, Medline Bag Decanter (K250345), is substantially equivalent to the predicate device, GCMEDICA Bag Transfer Device (K182819), with respect to safety and effectiveness of the device in accordance with its intended use.