September 16, 2025

Microtek Medical LLC
% Prithul Bom
Most Responsible Person
REGULATORY TECHNOLOGY SERVICES, LLC
1000 Westgate Drive, Suite #510k
Saint Paul, MN 55114

Re: K251676
Trade/Device Name: Medline Microtek C-Flo Bag Decanter, Sterile (2000S); Medline Microtek Bag Decanter II, Sterile (2002S); Medline Microtek Vial Decanter, Sterile (2006S); Medline Microtek Transfer Device, Sterile (2008S)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: September 8, 2025
Received: September 8, 2025

Dear Prithul Bom:

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.*

Submission Number *(if known)*

K251676

Device Name

Medline Microtek C-Flo Bag Decanter, Sterile (2000S);
Medline Microtek Bag Decanter II, Sterile (2002S);
Medline Microtek Vial Decanter, Sterile (2006S);
Medline Microtek Transfer Device, Sterile (2008S)

Indications for Use *(Describe)*

Microtek decanters are intended for the aseptic transfer of solutions (eg. IV fluids and medications) from IV containers

- Bag decanters are for use in transferring IV fluids and medication from a bag to an IV fluid administration device.
- Vial decanters are for use in transferring IV fluids and medications from a vial to an IV fluid administration device.
- Transfer devices are for use in transferring IV fluids and medications from a vial or medication container to an IV fluid administration device.

Microtek decanters are suitable for adult and pediatric patients. The use of decanters is at the discretion of the healthcare professional.

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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**K251676 - 510(k) Summary**

**Submitter**

510(k) submitted by:
Microtek Medical LLC
Three Lakes Drive
Northfield, IL 60093
Establishment Registration Number: 3014342658

Contact person:
Lam Duong
Senior Manager Regulatory Affairs
Phone: (651) 412 6559
Email: LDuong@medline.com

**Submission Date:** 15 September 2025

**Device**

The following trade names are applicable to the devices
Medline Microtek C-Flo Bag Decanter, Sterile (2000S)
Medline Microtek Bag Decanter II, Sterile (2002S)
Medline Microtek Vial Decanter, Sterile (2006S)
Medline Microtek Transfer Device, Sterile (2008S)

The common or usual names for this type of product:
I.V. Fluid Transfer Set

Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Product Code: LHI
Classification Panel: General Hospital
Device Classification: Class II

Submission Type: 510(k) Traditional

**Primary Predicate Device**
GCMEDICA Transfer Device (K182819)

**Device Description**

Microtek decanters and transfer devices are provided sterile and for use in a single procedure only. They consist of a hollow tube with protective removable caps at either end. The injection molded hollow tube has at least one spiked end used to access the source container to initiate fluid transfer. The vial decanter includes a built-in splash guard.

Decanters and transfer devices are designed to transfer medical fluids (e.g.: medications and solutions) between various containers. Below is a summary of the different configurations.

| Model Number(s) | Description | Container Configuration | Overall Length (of finished device without caps) | Materials |
|---|---|---|---|---|
| 2000S | C-Flo Bag Decanter, Sterile | Bag to an IV fluid administration device | 8.25” | PMMA |
| 2002S | Bag Decanter II, Sterile | Bag to an IV fluid administration device | 8.25” | HIPS825 |
| 2006S | Vial Decanter, Sterile | Vial to an IV fluid administration device | 6” | HIPS825, ABS |
| 2008S | Transfer Device, Sterile | Vial or medication container to an IV fluid administration device | 3” | ABS |

**Indications for Use**

Microtek decanters are intended for the aseptic transfer of solutions (eg. IV fluids and medications) from IV containers

- Bag decanters are for use in transferring IV fluids and medication from a bag to an IV fluid administration device.
- Vial decanters are for use in transferring IV fluids and medications from a vial to an IV fluid administration device.
- Transfer devices are for use in transferring IV fluids and medications from a vial or medication container to an IV fluid administration device.

Microtek decanters are suitable for adult and pediatric patients. The use of decanters is at the discretion of the healthcare professional.

**Substantial Equivalence**

Microtek decanters are medical fluid transfer devices with the same intended use as the predicate device: GCMEDICA Transfer Device.

There are a variety of medical fluid transfer devices on the market covering a wide range of materials and designs. The use of the spike and tube facilitates a sterile path for the medical fluid to flow through. Decanting or transfer devices help ensure the aseptic transfer of medical fluids from one container to another.

| Device Name | Proposed Device: Microtek decanting and transfer devices | GCMEDICA Transfer Device (various models) | Comparison Analysis |
|---|---|---|---|
| **Regulation Number** | 21 CFR 880.5440 | 21 CFR 880.5440 | Same |
| **Product Code** | LHI | LHI | Same |
| **Premarket Notification** | New Device | K182819 | N/A |

| | | | |
|---|---|---|---|
| **Indications for Use** | Microtek decanters are intended for the aseptic transfer of solutions (eg IV fluids and medications) from IV containers.<br>• Bag decanters are for use in transferring IV fluids and medication from a bag to an IV fluid administration device.<br>• Vial decanters are for use in transferring IV fluids and medications from a vial to an IV fluid administration device.<br>• Transfer devices are for use in transferring IV fluids and medications from a vial or medication container to an IV fluid administration device. | • Bag Transfer Devices: 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.<br>• Vial Transfer Devices: Intended for the aseptic dispensing of solutions from IV containers. For use in transferring IV fluids/medication from a vial to an IV fluid administration device. | Same |
| **Intended Patient Population** | Microtek decanters are suitable for adult and pediatric patients. The use of decanters is at the discretion of the healthcare professional. | None stated / general population | Similar. Microtek decanters meet EO residual level for adult and pediatric patients, including infants and neonates. |
| **Device Materials** | 2000S: PMMA<br>2002S: HIPS825<br>2006S: HIPS825, ABS<br>2008S: ABS | GC0652DD, GC0653DD, GC0654DD: ABS, PE<br>GC0654DT: K Resin, PE | Similar polymer based plastic materials. Biocompatibility testing was performed on subject devices per ISO 10993-1. The differences do not raise any question regarding the device safety or effectiveness. |
| **Operating principle** | • Aseptic transfer of medical fluids<br>• Spike and tube to facilitate fluid flow | • Through the use of a spike/stick, facilitates creation of a sterile path<br>• Decanting device helps ensure an aseptic transfer or removal of fluids/medication | Same |
| **Sterilization** | EO | EO | Same |

| | | | |
|---|---|---|---|
| **Device components/ features** Spike, tube, splashguard, caps | • Bag Decanters (2000S, 2002S) consists of one spike, tube and caps for ends<br>• Vial Decanters (2006S) consists of one spike, tube, splashguard, and caps for ends<br>• Transfer Device(2008S) consists of two spikes and caps for spikes | • GC0654DT and GC0654DD consist of one spike, tube and caps for ends<br>• GC0653DD consists of one spike, tube, splashguard and caps for ends<br>• GC0652DD consists of two spikes and caps for spikes | Same |
| **Length** | • 2000S, 2002S: 8.25”<br>• 2006S: 6”<br>• 2008S: 3” | • GC0654DT: 9”<br>• GC0654DD: 9”<br>• GC0653DD: 6”<br>• GC0652DD: 3” | No significant differences. Any slight length differences do not raise any question regarding the device safety or effectiveness. |
| **Biocompatibility** Test to ISO 10993-1 and applicable parts of series | • ISO 10993-1:2018<br>• ISO 10993-4:2017<br>• ISO 10993-5:2009<br>• ISO 10993-10:2021<br>• ISO 10993-11:2017<br>• ISO 10993-23:2021 | • ISO 10993-1:2009<br>• ISO 10993-4:2017<br>• ISO 10993-5:2009<br>• ISO 10993-10:2010<br>• ISO 10993-11:2017 | No significant differences. Biocompatibility testing did not raise any question regarding device safety. |

The proposed Microtek decanters and transfer devices are substantially equivalent in intended use, device characteristics, device design and function in comparison to the predicate devices. As reflected in the Substantial Equivalence Comparison Table, there are no significant differences when comparing the proposed devices to the predicate devices. Functional performance and material biocompatibility testing included within this 510(k) supports the safety and effectiveness of the proposed devices and further verifies predicate equivalence.

**Technological characteristics**

Information included in this submission demonstrates that there are no significant differences in technological characteristics between Microtek decanting and transfer devices and the cited predicate devices.

**Sterilization**

The Microtek decanters and transfer devices are sterilized by terminal ethylene oxide sterilization. The method used for this validation study is the half cycle approach referenced in Annex B Overkill approach of ISO 11135:2014. Sterility Assurance Level (SAL) = $10^{-6}$

- Ethylene Oxide residuals ≤ 0.21 mg, in accordance with ISO 10993-7 for limited exposure devices.

- Ethylene Chlorohydrin levels ≤ 0.45 mg, in accordance with ISO 10993-7 for limited exposure devices.

**Biocompatibility**

The biocompatibility evaluation for this device was conducted in accordance with ISO 10993-1:2018, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process, as recognized by FDA.

The following Biocompatibility tests were conducted on the clear bag decanter and a vial decanter. The results of all testing were passing.

| **Biocompatibility Test** | **Standards** |
|---|---|
| In Vitro Hemocompatibility Testing (Rabbit blood) Standard practice for Assessment of Hemolytic Properties of Materials | ISO 10993-4:2017<br><br>ASTM F756-17 |
| In Vitro Cytotoxicity Test | ISO 10993-5:2009 |
| Skin Sensitization Test: Guinea Pig Maximization Test (0.9% Sodium Chloride Injection Extract) | ISO 10993-10:2021 |
| Skin Sensitization Test: Guinea Pig Maximization Test (Sesame oil Extract) | ISO 10993-10:2021 |
| Acute Systemic Toxicity (0.9% Sodium Chloride Injection Extract, Intravenous) | ISO 10993-11:2017 |
| Acute Systemic Toxicity (Sesame Oil Extract, Intraperitoneal) | ISO 10993-11:2017 |
| Pyrogen Test (0.9% Sodium Chloride Injection Extract, Rabbit) | ISO 10993-11:2017 |
| Intracutaneous Reactivity Test (0.9% Sodium Chloride Injection Extract and Sesame Oil Extract) | ISO 10993-23:2021 |

**Performance Testing**

The Microtek decanters and transfer devices have been tested for the dimensional requirement of closure piercing per ISO 22413:2021 and all other relevant performance requirements in accordance with ISO 8536-4:2019. All performance testing on the subject devices has demonstrated that they meet the necessary safety and efficacy standards, establishing equivalence to the proposed predicate devices.

**Risk Management**

The design and use risks for the Microtek decanters and transfer devices were evaluated using a process compliant with ISO 14971:2019. After application of risk control, all risks identified in the risk assessment were deemed to be broadly acceptable.

**Conclusion**

In accordance with 21 CFR Part 807 and based on the information provided in this premarket notification, Microtek Medical LLC concludes that the Microtek decanters and transfer devices are as safe, as effective and substantially equivalent to predicate devices in terms of intended use, device characteristics, device design, function and biocompatibility as described herein.