January 9, 2026

Fresenius Kabi AG
% Rhoda Valera
Senior Director, Regulatory Affairs
Fresenius Kabi
Three Corporate Dr.
Lake Zurich, Illinois 60047

Re: K251139
Trade/Device Name: KabiHelp® Uno; KabiHelp® Advance plus
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. container
Regulatory Class: Class II
Product Code: KPE
Dated: December 10, 2025
Received: December 10, 2025

Dear Rhoda Valera:

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)*
K251139

Device Name
KabiHelp® Uno
KabiHelp® Advance plus

Indications for Use *(Describe)*
The KabiHelp® Bag is an empty container to be filled with components of parenteral nutrition and parenteral nutrition related medication to be administered to the patients using an intravascular administration set. Parenteral nutrition and parenteral nutrition related medication transfer in and out of the container is done using aseptic technique.

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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January 9, 2026

K251139 - 510(k) Summary

Contact Details

Applicant Name	Fresenius Kabi AG
Applicant Address	Else-Kröner-Str. 1 Bad Homburg 61352 Germany
Correspondent Name	Fresenius Kabi
Correspondent Address	Three Corporate Drive Lake Zurich, IL 60047 United States
Correspondent Contact Telephone	847-550-2929
Correspondent Contact	Rhoda Lynn Valera
Correspondent Contact Email	rhoda.valera@fresenius-kabi.com

Device Name

Device Trade Name	KabiHelp® Uno KabiHelp® Advance plus
Common Name	I.V. container
Classification Name	Container, I.V.
Regulation Number	880.5025
Product Code	KPE

Legally Marketed Predicate Device

Predicate 510(k) Number	K210749
Predicate Trade Name	Empty EVA Bag
Product Code	KPE

Device Description Summary

The KabiHelp® Bag is an empty plastic container to be filled with components of parenteral nutrition and parenteral nutrition related medication to be administered to patients using an intravascular administration set. It is designed to be used with KabiHelp Pro Compounding System and KabiHelp Transfer Sets and Accessories.

Filling of the bags takes place in an aseptic environment. The bags are available in monolayer or multilayer models in various volumes.

All KabiHelp bags are equipped with three port types: (1) a filling port suitable for the KabiHelp Transfer Sets, (2) an injection port for manual injection of additives, and (3) an administration port for infusion therapy.

Intended Use/Indications for Use

The KabiHelp® Bag is an empty container to be filled with components of parenteral nutrition and parenteral nutrition related medication to be administered to the patients using an intravascular administration set. Parenteral nutrition and parenteral nutrition related medication transfer in and out of the container is done using aseptic technique.

Indications for Use Comparison

The Indications for Use between the subject device and the predicate device is the same as they are both used for solution preparation and administration using aseptic technique. The KabiHelp bag is used for parenteral nutrition components and parenteral nutrition-related medication, which do not constitute a new intended use.

Technological Comparison

The following table provides a comparison between the subject and predicate devices:

Description	**Subject Device KabiHelp Bag**	**Predicate Device Empty EVA Bag (K210749)**	**Discussion**
Indications for Use	The KabiHelp Bag is an empty container to be filled with components of parenteral nutrition and parenteral nutrition related medication and to be administered to the patients using an intravascular administration set. Parenteral nutrition and parenteral nutrition related medication transfer in and out of the container is done using aseptic technique.	The Empty EVA Bag is an empty container used for administration of solutions to the patients using an intravascular administration set. Medication transfer in and out of the container is done using aseptic technique.	Different Slight verbiage difference but both are used for solution preparation and administration using aseptic technique.

Description	Subject Device KabiHelp Bag	Predicate Device Empty EVA Bag (K210749)	Discussion
Regulation Number	880.5025	880.5025	Same
Product Code	KPE	KPE	Same
Classification Name	I.V. Container	I.V. Container	Same
Material	EVA (Ethylene vinyl acetate) PVC (Polyvinyl Chloride) ABS (Acrylonitrile Butadiene Styrene) PS (Polystyrene) EVOH (Ethylene vinyl alcohol) Blue Ink While Dye Green Dye	EVA (Ethylene vinyl acetate) PVC (Polyvinyl Chloride) ABS (Acrylonitrile Butadiene Styrene) PP (Polypropylene) SBC (Styrene Butadiene Copolymer) MABS (Methyl Methacrylate Acrylonitrile Butadiene Styrene) Thermoplastic Elastomer Yellow Dye Blu Dye	Different The biocompatibility data provided demonstrates that the subject device is as safe and effective as the predicate device, and the material differences do not raise any new issues of safety and effectiveness.
Biocompatibility	Meet requirements for ISO 10993-1	Meet requirements for ISO 10993-1	Same

Description	Subject Device KabiHelp Bag	Predicate Device Empty EVA Bag (K210749)	Discussion
Design	The KabiHelp Bag has the following configuration: - with three tubes: (1) a fill port to fill the container (2) injection port for additions of other medications and (3) a spike port to connect intravascular administration set; after filling the bag is clamped by means of non-reopening clamp to secure the contents before administration. The KabiHelp Bag is available in monolayer EVA or multilayer EVA/EVOH.	The Empty EVA bag has the following configurations: - with three tubes: (1) a fill port to fill the container, (2) injection port for additions of other medications and (3) a spike port to connect intravascular administration set; after filling the bag is clamped by means of non-reopening clamp to secure the contents before administration. - with one tube, used both for the filling of the bag and the administration of the solution to the patient; after filling the bag is clamped by means of a pinch clamp and closed with the sealing cap to secure the contents prior to Administration. The Empty EVA Bag is available in monolayer EVA.	Different The subject device and the predicate device both offer a three-tube configuration with the same types of ports. Both devices also offer a monolayer EVA variant. The scientific data provided demonstrates that the subject device is as safe and effective as the predicate device, and the variant differences do not raise any new issues of safety and effectiveness.
Sterilization	SAL 10^{-6}, Ethylene oxide (EO) sterilization	SAL 10^{-6}, Radiation	Different The subject device and the predicate device have the same Sterility Assurance Level (SAL). EO and Radiation belong to the same Established Category A sterilization method.
Reusable	No	No	Same

Description	Subject Device KabiHelp Bag	Predicate Device Empty EVA Bag (K210749)	Discussion
Packing Pouch	Tyvek for EO sterilization	Polyethylene (LDPE) for gamma sterilization	Different The sterilization data provided demonstrates that the subject device is as safe and effective as the predicate device, and the packaging material difference does not raise any new issues of safety and effectiveness.

The technological characteristics of the subject device were compared with publicly available information on the predicate device. Differences were analyzed and verified through testing, showing no additional concerns and demonstrating that the subject device is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The nonclinical tests were conducted on the subject device according to the following standards in order to demonstrate substantial equivalence with the predicate device:

1. Biocompatibility Testing according to ISO 10993-1:2018 Biological evaluation of medical devices, Evaluation and testing within a risk management process. The following biocompatibility tests were performed:
   - Cytotoxicity ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for invitro-cytotoxicity
   - Sensitization ISO 10993-10:2021 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
   - Irritation or Intracutaneous Reactivity ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Test for irritation
   - Acute Systemic Toxicity ISO 10993-11:2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
   - Subacute/Subchronic Toxicity ISO 10993-11:2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
   - Material-Mediated Pyrogenicity USP <151> Pyrogen Test (Rabbit Test)
   - Hemolysis ASTM F756:2017 Standard Practice for Assessment of Hemolytic Properties of Materials
2. Applicable Requirements according to ISO 15747:2018 Plastic containers for intravenous injection
3. Particulate matter according to USP <788> Particulate Matter in Injections
4. Chemical testing according to ISO 15747:2018 Plastic containers for intravenous injections

5. The package integrity testing according to ISO 11607-1:2019 Packaging for terminally sterilized medical devices – Requirements for materials, sterile barrier systems and packaging systems
6. Human Factors Study according to Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff, issued February 2016

No clinical study has been conducted on the subject device.

Substantial Equivalence

All the necessary safety and performance tests conducted on the subject device demonstrated that the KabiHelp Bag is substantially equivalent to the predicate device, particularly regarding its intended use and technological characteristics. The minor differences between the devices do not raise any new issues of safety or effectiveness.