April 18, 2025

Technoflex SAS.
% Vaibhav Rajal
Senior Regulatory Affairs Consultant
mdi Consutants, Inc.
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K250459
Trade/Device Name: DMRX 100ml Empty Container Solution; DMRX 250ml Empty Container Solution; DMRX 500ml Empty Container Solution; DMRX 1000ml Empty Container Solution
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. Container
Regulatory Class: Class II
Product Code: KPE
Dated: February 13, 2025
Received: February 18, 2025

Dear Vaibhav Rajal:

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, 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)*

K250459

Device Name

DMRX 100ml Empty Container Solution;
DMRX 250ml Empty Container Solution;
DMRX 500ml Empty Container Solution;
DMRX 1000ml Empty Container Solution

Indications for Use *(Describe)*

The TECHNOFLEX DMRX Empty solution container is empty container used for administration of intravenous solutions to the patient using an intravascular administration set.
Medication transfer in and out of the container is done using aseptic technique.
After use the bag is discarded.

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.

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TECHNOFLEX
The IV drug delivery expert

K250459 - 510(k) SUMMARY

1. **Submitter's Information**

TECHNOFLEX SAS.
ZA de Bassilour
4210 Bidart, France
Contact: Dominique Saint Ellier
Q & RA Director
Phone: +33 559546666
Fax: +33 5 59 54 90 06
Email: d.saintellier@tachnoflex.net
Date Summary Prepared: April 18, 2025

2. **Trade Name of the Device:** DMRX 100mL EMPTY CONTAINER SOLUTION
DMRX 250mL EMPTY CONTAINER SOLUTION
DMRX 500mL EMPTY CONTAINER SOLUTION
DMRX 1000mL EMPTY CONTAINER SOLUTION

3. **Common or Usual Name:** I.V. Container

4. **Classification Name:** I.V.container
Regulation Number: 880.5025
Product Code: KPE
Panel: General Hospital

5. **Predicate Device Information:**
Gilero, LLC, SmartSite Bag 500mL, SmartSite Bag 250 mL, SmartSite Bag 100 mL, K201936

6. **Device Description**
The subject device DMRX Empty Solution Container are IV bags for hospital use which consist of two tubes necessary for the filling of the bag itself and the administration of the solution to the patient.

a) fill port to fill the container/injection port for additions of other medications and;
b) a spike port to connect an intravascular administration set to the bag to dispense medication.

One port is an injection port, which will be used for filling the bag with the solution. The filling will be

made with a needle, using aseptic technics by a laboratory personnel or pharmacist. The elastomeric plug is auto sealable and does not require a cap after filling. The administration will be performed by nurses or personnel appropriately trained. They will connect an administration set to the second port which is a twist-off port (spike port).

The device is an empty flexible container (bag) made of PP (Polypropylene), SEBS (Styrene Butadiene Copolymer), Thermoplastic Elastomer, PC (Polycarbonate), and Polyisoprene with silicone. One port is an injection port. The empty bag is filled by connecting a needle into the injection port. Using aseptic technics by a trained laboratory personnel or pharmacist, the filling is done by the tube with the injection port connector. After filling, the bag remains closed due to the self-sealing plug which secures the contents prior to administration. To make the fluid outflow from the bag towards the patient, the bag is connected to an intravascular administration set via the second port (spike port). When the bag is already filled, other medications can be added using the injection port.

The device will be available in four containment volumes (100mL, 250mL, 500mL, and 1000mL). Bags are double packed and proposed sterilized with e beam radiation.

7. Indications for use Statement:

The TECHNOFLEX DMRX Empty solution container is empty container used for administration of intravenous solutions to the patient using an intravascular administration set.
Medication transfer in and out of the container is done using aseptic technique.
After use the bag is discarded.

8. Technological Comparison to Predicate Devices:

The subject device Technoflex DMRX 100mL Empty Solution Container, DMRX 250mL Empty Solution Container, DMRX 500mL Empty Solution Container, and DMRX 1000mL Empty Solution Container is substantially equivalent to 510(k) cleared Gilero, LLC (SmartSiteTM Bag), K201936 device.

Item	Subject Device (K250459)	Predicate Device (K201936)	Comments
Manufacturer	TECHNOFLEX	GILERO, LLC	Different The device has been tested as described in the below discussion
Proprietary / Trade Name	DMRX Empty solution container	SmartSiteTM Bag	Different The device has been tested as described in the below discussion

Indications for use Statement	The TECHNOFLEX DMRX Empty solution container is empty container used for administration of intravenous solutions to the patient using an intravascular administration set. Medication transfer in and out of the container is done using aseptic technique. After use the bag is discarded.	The SmartSiteTM Bag is an empty container used for administration of intravenous solutions to the patient using an intravascular administration set. Medication transfer in and out of the container is done using aseptic technique.	Substantially Equivalent
Intended User	Laboratory technicians, Pharmacists, pharmacy technicians, hospital staff nurses, and homecare nurses	Laboratory technicians, Pharmacists, pharmacy technicians, hospital staff nurses, and homecare nurses	Identical Both the subject device and the predicate device are intended to be used by personnel appropriately trained and authorized to use bags for medication preparation and delivery
Principle of Operation	Empty bags are filled by connecting a needle to containers containing one or	Empty bags are filled by connecting to containers containing one or more	Different Both the subject device and predicate

	more solutions through the add port (injection port). The self-closing add port does not require clamping to secure the contents. Contents are secured through the passive action of the add port. IV sets can be attached to the spike port (twist-off port) to facilitate delivery of the medication to the patient	solutions through the add port. The self-closing add port does not require clamping to secure the contents. Contents are secured through the passive action of the add port. IV sets can be attached to the spike port, or the add port to facilitate delivery of the medication to the patient.	device are filled by the user through an add port. The subject device is filled with a needle whereas the predicate device is filled with a luer lock connection. Both the subject device and predicate device contain a spike port to connect an IV administration set for delivery of the medication to the patient. The predicate device also allows the user to connect the IV administration set to the add port These differences present no new questions of safety or effectiveness when compared to the predicate, since both the subject and predicate devices provide a mechanism for safe filling of the bag and administration of the medication to the patient using an IV administration set.

Material composition	Layflat INERTA 103 material (PP based with SEBS) Tubing APP 107 (PP based with SEBS) INERTA 016 granula (PP homopolymer) Injection site (Polycarbonate, PP INERTA membrane and Polyisoprene elastomeric plug)	Layflat INERTA 103 material (PP based with SEBS) Tubing APP 107 (PP based with SEBS) INERTA 016 granula (PP homopolymer) Smartsite (Acrylic, Polyurethane and silicone plug)	Equivalent Material used for the bag manufacturing is strictly the same except for the add port. The subject device prevents contact of the solution with the elastomeric part of the plug whereas the solution is in direct contact with the silicone part of the add ort. The membrane placed inside the add port of the subject device is same material that this use for the bag.
Technology and design	The device includes a spike port (twist-off port) and the add port (injection port). The add port allows for medication(s) to be added to the bag. An IV administration set can be connected to the bag to dispense medication	The device includes a spike port and the add port. The add port allows for medication(s) to be added to the bag. An IV administration set can be connected to the bag to dispense medication	Substantially Equivalent Both the subject and predicate device include design features to allow the user to fill the bag and attach an IV administration set for delivery of the medication.

Sizes	100mL, 250mL, 500mL, and 1000mL	100mL, 250mL and 500mL	Different
Biocompatibility	Meet requirements for ISO 10993-1	Meet requirements for ISO 10993-1	Substantially Equivalent
Sterilization	SAL 10^{-6} radiation ebeam	SAL 10^{-6} radiation ebeam	Substantially Equivalent

Reuse	Single-use only	Single-use only	Substantially Equivalent
Patient Population	Adults and children	Adults and children	Same

Discussion of Similarities and Differences:

Similarities

- Both the subject devices, including the Technoflex DMRX 100mL Empty Solution Container, DMRX 250mL Empty Solution Container, DMRX 500mL Empty Solution Container, and DMRX 1000mL Empty Solution Container, as well as the predicate device from Gilero, LLC (SmartSite™ Bag), are similar in both design and intended use. Both sets of devices are intended for single use and feature chamber containers with two ports. Additionally, both devices facilitate the filling and administration of a drug or solution.
- The subject device and the predicate device share identical indications for use, similar intended uses, and serve comparable patient populations and user groups. Both devices are labeled as sterile and are designated as single-use only.
- The materials used in the construction of both the subject and predicate devices are largely identical, with the primary difference being the inclusion of an add port in the subject devices. The add port, already widely used in drug applications, has been evaluated through ISO 10993 testing or equivalent documentation to demonstrate material safety.
- Moreover, both the subject and predicate devices incorporate add ports, which enable users to fill the solution container as needed. Additionally, both devices are equipped with mechanisms for attaching an IV administration set, allowing for the safe and efficient delivery of medication to the patient.

Differences

The subject device and the predicate are different in principle of operation and size. In terms of the design, the addition port on the subjects' device is different from the predicate. The predicate device uses a smart site that allows addition and administration of the container I.V. whereas, the injection site used in the subject device allows only for the addition of solution. The subject device proposes size variations in the volume of 100mL, 250mL, 500mL and 1000 mL. The available size of the predicate is 100mL, 250mL, and 500mL.

The only technological difference between the subject and predicate devices is the add ports. The predicate device contains an add ports with a luer lock connection for initial fill of the bag. The subject device has an

add port that is used by piercing the elastomeric part of the port with a needle.
Both add port of the two devices do not need a clamp after using. The Predicate device has a silicone valve while elastomeric plug of the subject device is auto sealable preventing leaks.

Use of Environment

The use environment of the bag is described in the following tables (See Table 3 and Table 4).

Table 3 : conditions of use of the DMRX Empty Solution Container

Consideration	Features
Sterility / cleanliness level	Sterile
Single use / reusable / reprocessed	Single use
Hospital / Home use	Hospital
Ambient lighting	Ambient to intensive lighting
Noise level	Low noise level
User's personal protective equipment	Use protection describe in hospital procedure
Other instruments / products used in concert	Perfusion line and spike

Table 4 : Use environment of the DMRX Empty Solution Container according to the lifecycle steps

Lifecycle steps	Use environment
Transport	Shipment container
Storage	Storage room at the users' sites, pharmacy
Use (filling)	Pharmacy at the hospital, compounders
Use (administration)	Hospital
Elimination	Hospital

Conclusion

Although the DM RX Empty Solution Container exhibits certain design differences when compared to the predicate device, these differences do not alter the intended use or raise new questions regarding safety and effectiveness. Based on the attached test reports and supporting documentation, all identified differences have been thoroughly evaluated and do not present any concerns related to safety or effectiveness.

9. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The following non-clinical tests were performed to demonstrate the substantial equivalence to the predicate device:

Biocompatibility:

The predicate device, was evaluated for biocompatibility appropriate to the contact characterization (External communicating device, Blood path, indirect, B-prolonged), in accordance with the requirements of ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and the FDA Guidance for Industry - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

The subject device is composed of same material (except the add port) and biocompatibility tests has been performed to be comparable to the predicate. The subject device was evaluated for biocompatibility per the guidelines of ISO 10993-1 for the contact characterization of the device.

- ISO 10993-4 Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood
- ISO 10993-5 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices Part 10: Tests for skin sensitization
- ISO 10993-11 Biological evaluation of medical devices Part 11: Tests for Systemic Toxicity
- ISO 10993-18 Biological evaluation of medical devices Part 18: Chemical Characterization of medical device materials within a risk management process
- USP <40> Hemocompatibility Assessment
- USP <85> Bacterial Endotoxin tests
- USP <88> Biological Reactivity of Materials
- USP <161> Bacterial Endotoxin and Pyrogen tests
- USP <1663> Assessment of Extractables associated with Pharmaceutical Packaging/Delivery Systems

Performance Testing:

The subject device was performance tested via the below standard:

- ISO 15747-4 Plastic Containers for intravenous injections

Sterilization Testing:

The DM RX Empty solution container is sterilized using irradiation in accordance with a validated sterilization cycle. The following standards were referenced during the sterilization validation process:

- ANSI/AAMI/ISO 11137-1:2006/(R) 2015&A1 2013 Sterilization of Health Care Products-Radiation-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 11137-2:2013/(R) 2019 Sterilization of Health Care Products-Radiation-Part 2: Establishing the sterilization dose

- ANSI/AAMI/ISO 11137-3:2017 (R2023): Dosimetry

Particulate Testing:
The DM RX Empty solution container was tested to demonstrate the product meets particulate requirements of USP <788>
Additional testing was conducted to demonstrate:

- Bag integrity (leakage)
- Performance after simulated shipping
- Shelf life
- Microbial Ingress Testing

Packaging testing:
The subject device's packaging seal was tested per the below standard:

- EN868-5 Packaging materials Heat Self-Sealable Pouches Plastic Film Strength testing

Other Testing Performed:
The subject device was also tested to demonstrate compliance with the following:

- Drop resistance
- Self-sealing capability

11. Conclusion

The information in this submission supports that the subject device is as safe and effective as the predicate device for its intended use and demonstrates substantial equivalence with the predicate device. The DM RX empty solution container differences in materials, technology and operation from the predicate device do not raise new questions about safety and effectiveness.