February 15, 2019

Valmed SRL
% Tiziana Baggio
Consultant
Studio Baggio Tiziana
Via Marzia 9
Abano Terme, Padova 35031
Italy

Re: K181393
Trade/Device Name: Empty Eva Bag, models FVM0134BP, FVM0135BP, FVM0136BP, FVM0137BP, FVM0138BP, FVM0139BP, FVM0140BP, FVM0141BP
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. Container
Regulatory Class: Class II
Product Code: KPE
Dated: January 16, 2019
Received: January 18, 2019

Dear Tiziana Baggio:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K. Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K181393

Device Name
Empty EVA Bag, models FVM0134BP, FVM0135BP , FVM0136BP , FVM0137BP, FVM0138BP, FVM0139BP, FVM0140BP, FVM0141BP

Indications for Use *(Describe)*
The Empty EVA 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

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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510(k) Summary K181393

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Date Summary Prepared: January 16, 2019

DEVICE IDENTIFICATION

Trade name:	Empty EVA Bag, models FVM0134BP, FVM0135BP, FVM0136BP, FVM0137BP, FVM0138BP, FVM0139BP, FVM0140BP, FVM0141BP
Generic/Common Name:	empty I.V. bag
Regulation number:	21 CFR §880.5025 Class II
Regulation name:	I.V. Container
Product Code:	KPE
Panel:	General Hospital

PREDICATE DEVICE:
Valmed identified the following legally marketed device as substantially equivalent:

- EVA TPN Bags, Valmed S.R.L., K101412

DEVICE DESCRIPTION:
The Empty EVA 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.

The empty bags are filled by connecting them to containers – generally glass bottles closed by a pierceable membrane - containing one or more solutions through standard spikes and tubing. After filling, the transfer set is removed and the bags are clamped by means of inviolable clamps to secure the contents prior to their administration. To make the fluid outflow from the bag towards the patient, the container can be then attached to an intravascular administration set via the spike port and twist-off connector.

When the bag is already filled, other medications can be added using the injection port. The bags range in volume capacity from 150 ml to 5000 ml.

The device is sold sterile and cannot be re-used or re-sterilized; it is discarded after use. The Empty EVA Bag is intended for use by qualified staff.

INDICATIONS FOR USE:
The Empty EVA 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.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:
In support of a substantial equivalence determination, hereunder is a comparison chart with the submitted device and the predicate device.

Feature	EMPTY EVA BAG (Submitted Product)	PREDICATE DEVICE	CONCLUSION
K number	K181393	K101412	
Proprietary / Trade Name	Empty EVA Bag	EVA TPN Bags	
Manufacturer	VALMED S.R.L.	VALMED S.R.L.	
CFR Section	880.5025	880.5025	substantially equivalent
Product code	KPE	KPE	substantially equivalent
Classification	I.V. Container, General Hospital	I.V. Container, General	substantially equivalent
Indications For Use	The Empty EVA 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.	The EVA TPN bag is for use in compounding and storage of parenteral nutrition solutions prior to and during administration to a patient using an intravascular administration set.	The subject device and the predicate device are similar in their intended use, they are both used in administration of solutions to patient using an intravascular administration set. The IFU for general use of the subject device – in comparison to the narrower IFU (parenteral nutrition solutions) of the predicate device - does not impact on safety and effectiveness of the device, as both the devices are made of the same material. The additional biocompatibility tests performed on the subject device to assess the subacute/subchronic toxicity endpoints as well as the variety of non-clinical tests performed on the Empty Eva Bags demonstrate that the proposed general IFU raises no different safety and effectiveness questions as compared to its predicate device.
Intended Users	Adequately trained staff	Adequately trained staff	substantially equivalent
Design	The EVA bags include an outflow tube and a connector to the transfer set. Additional medications can be added to the container using the medication port. A capsule closes the medication port after use. The bags are clamped after filling by means of inviolable clamps.	The TPN bag includes an outflow tube and a connector to the transfer set. Additional medications can be added to the container using the medication port. A capsule closes the medication port after use. The bags are clamped after filling by means of inviolable clamps.	The subject device and the predicate device have the same design, with fill port, injection port for additional medications, spike port for administration and inviolable clamp to be used after filling the bag.

MATERIALS:			
Bag body	EVA (not made with plasticizer Diethylhexylphthalate DEHP)	EVA (not made with plasticizer Diethylhexylphthalate DEHP)	same
Female connector	ABS (Acrylonitrile Butadiene Styrene)	ABS (Acrylonitrile Butadiene Styrene)	same
Male cap	ABS	ABS	same
Injection port	ABS (not made with natural rubber latex), Polyisoprene, Polypropylene	ABS (not made with natural rubber latex) Polyisoprene, Polypropylene	same
Spike port	PVC (not made with plasticizer Diethylhexylphthalate DEHP)	PVC (not made with plasticizer Diethylhexylphthalate DEHP)	same
Inviolable clamp	Polypropylene	Polypropylene	same
Biocompatibility	Meet requirements for ISO 10993-1	Meet requirements for ISO 10993-1	substantially equivalent
Sterilization	SAL 10-6, ETO	SAL 10-6, ETO	same
Reusable	No	No	same
Packing Blister Pouch	Polyester / Polypropylene (PET / PP) - medical grade paper	Polyester / Polypropylene (PET / PP) - medical grade paper	same

SUBSTANTIAL EQUIVALENCE DISCUSSION:

The Empty EVA Bags are same or similar in materials, design and intended use to the predicate device (K101412).

The indications for use for the predicate device (TPN solution) are narrower in comparison to the proposed indications for use for the subject device (general intravenous solution). This difference in the indications for use between the subject device and the predicate devices is not critical since both the devices are empty containers made of Ethylene Vinyl Acetate (EVA) material intended for administration of solutions to patient using an intravascular administration set.

Expanding the IFU from TPN to general use does not affect the safety and effectiveness of the device, as also proved by the additional biocompatibility tests performed on the subject device to assess the subacute/subchronic toxicity endpoints considering that patients may repeatedly use the Empty EVA Bag and its replacements for general intravenous solutions.

The non-clinical tests performed on the Empty Eva Bags demonstrate that the proposed general IFU raises no different questions of safety and effectiveness as compared to its predicate device.

The subject device has the same technological characteristics and design as the predicate device: both the devices include a tube and a connector to the transfer set, an inviolable clamp that closes the bag outflow after transfer, an injection port which allows injection of fluids when the bag is already filled and a spike port which allows the fluid to outflow from the bag towards the patient for administration.

The Empty EVA Bags cannot be used for more than 24 hours and are intended for use by qualified staff, just as the predicate device.

DISCUSSION OF NON CLINICAL TESTS

Non clinical tests were conducted to demonstrate substantial equivalence to the predicate device. The test results demonstrated that the proposed device complies with the applicable sections of the standards listed below:

Biocompatibility:

The materials used to manufacture the subject device are the same as those used for the predicate device.

Biocompatibility has been tested according to the requirements of ISO 10993-1, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing"

The following biocompatibility tests were performed:

- Cytotoxicity, ISO 10993-5:2009: "Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity"
- Sensitization and Intracutaneous reactivity, ISO 10993-10: 2010: "Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization"
- Haemolysis, ASTM F756-13: "Standard Practice for Assessment of Haemolytic Properties of Material
- Hemocompatibility, ISO 10993-4:2009: "Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood"
- Subacute/Subchronic Toxicity, ISO 10993-11: "Biological evaluation of medical devices - Part 11: Tests for systemic toxicity"

Sterilization Validation:

Sterilization validation process was performed on the subject EVA Empty Bag according to Recognized Consensus Standard:

- AAMI / ANSI / ISO 11135-1:2014, Sterilization of health care products -Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

The subject device was tested for EO and ECH residuals according to:

- ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals.

Bacterial Endotoxin and Rabbit Pyrogen Testing:

LAL test was performed according to:

- USP 39th ed. 2016: <85> Bacterial Endotoxins Test
- USP 39th ed. 2016: <161> Transfusion and infusion assemblies and similar medical devices
- USP 38 <151> Pyrogen Test
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Performance tests:

The subject device was tested in order to verify compliance with:

- ISO 15747:2010 "Plastic containers for intravenous injections", as follows:
  Resistance to temperature stability and pressure, Resistance to leakage, Transparency, Water vapour permeability, Removal of injection site protection, Penetration ability, Tightness of the injection point, Tightness of the Hanger, Legibility of the characters, Particle Leak Test
- ISO 8536-4:2013 "Infusion equipment for medical use- Part 4: Infusion sets for single use, gravity feed"
- Evaluation of functional conformity in contact with "Sodium Chloride 0.9% water for injections"
- Evaluation of compatibility test (plastic migration) in contact with parenteral solution "ALL-IN-ONE solution" (OLIOCLINOMEL N4-550E-Baxter Healthcare)
- Evaluation of compatibility test (drug stability) in contact with parenteral solution "ALL-IN-ONE solution" (OLIOCLINOMEL N4-550E-Baxter Healthcare)

CONCLUSION:

Valmed believes that the submitted Empty EVA bag is substantially equivalent in its intended use, design, component materials, function, biocompatibility, sterility assurance level and packaging to the currently cleared predicate device based on the supported nonclinical testing.