August 19, 2021

Haemotronic S.p.a.
Paola Franciosi
QA Manager
Via Carreri 16
Mirandola, 41037
Italy

Re: K210749
Trade/Device Name: Empty EVA Bag
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. container
Regulatory Class: Class II
Product Code: KPE
Dated: July 16, 2021
Received: July 21, 2021

Dear Paola Franciosi:

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/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 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 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,

Payal Patel
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210749

Device Name
Empty EVA Bag

Indications for Use *(Describe)*
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.

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 - K210749

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Date Summary Prepared: August 18, 2021

DEVICE IDENTIFICATION

Trade name:	Empty EVA Bag
Generic/ Common Name:	I.V. Container
Regulation number:	21 CFR §880.5025 Class II
Regulation name:	I.V. container
Product Code:	KPE
Panel:	General Hospital

PREDICATE DEVICES:

Manufacturer: Haemotronic S.p.a.

Trade Name: Empty EVA Bag

510(k): K193528

DEVICE DESCRIPTION:

The product is an empty flexible container (bag) in plastic material, that is to be filled before use, intended for the administration of intravenous infusion solutions (IV solutions), and provided sterile.

It is provided in two different configurations, with three tubes or one tube:

- bag with 3 tubes:

  The empty bag is filled by connecting it to containers (generally glass bottles) filled with the solutions to be administered. The filling is done through the tube with the big bore connector where the non- re-opening clamp is located; this tube is closed with a screwed cap (air-tight closure). After filling, the bag is clamped by means of the non-re-opening clamp and closed with the sealing cap (screwed cap), to secure 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 access port (spike port). When the bag is filled, other drugs can be added using the second access port (injection port). The device is available in multiple containment volumes ranging from 250mL to 5000mL.

- bag with 1 tube:
  the bag is provided with one tube used both for the filling of the bag and the administration of the solution to the patient. The tube is closed with a screwed male Luer cap (air-tight closure). The filling is done by connecting the female Luer connector of the tube to the containers filled with the solutions to be administered. After filling, the bag is clamped by means of a pinch clamp and closed with the sealing cap (screwed cap), to secure the contents prior to administration. To make the fluid outflow from the bag towards the patient, the bag is connected to an intravascular administration line via the same female Luer connector. It is available in multiple containment volumes of 50mL, 100mL, and 250mL.

INDICATIONS FOR USE:

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.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL E Q U I V A L E N C E:

The side by side comparison between the subject and the predicate device shows that the two devices are similar in indications for use and in technological characteristics, and substantially equivalent in material composition. The minor differences in design and materials do not raise any concerns for safety and effectiveness.

Feature	EMPTY EVA BAG (Submitted Product)	PREDICATE DEVICE	COMPARISON
510(k) Number	K210749	K193528	
Proprietary / Trade Name	Empty EVA Bag	Empty EVA Bag	
Manufacturer	HAEMOTRONIC S.p.a.	HAEMOTRONIC S.p.a.	
Regulation Number	880.5025	880.5025	same
Product code	KPE	KPE	same
Classification name	I.V. Container	I.V. Container	same
Indications For Use	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.	The Empty EVA Bag is an empty container used for administration of TPN (Total Parenteral Nutrition) solutions to the patient using an intravascular administration set. Medication transfer in and out of the container is done using aseptic technique.	Different The subject device and the predicate device are similar in their indications for 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. Non-clinical testing was performed to demonstrate substantial equivalence. The biocompatibility tests as well as the functional and chemical tests performed demonstrate that the proposed larger IFU of the subject device raises no additional safety and effectiveness issues as compared to its predicate device.

Design	The Empty EVA bag is provided in two configurations: - with three tubes: a fill port to fill the container, injection port for additions of other medications and a spike port to connect intravascular administration set; after filling the bag is clamped by means of non re-opening 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 provided with three tubes: a fill port to fill the container, injection port for additions of other medications and a spike port to connect intravascular administration set. After filling, the bag is clamped by means of non re-opening clamp to secure the contents before administration.	Different The 3-tube configuration of the subject device has exactly the same technological characteristics and design of the predicate device, whereas the 1-tube configuration of the subject device has a different design. Biocompatibility per ISO 10993-1, chemical and performance testing per ISO 15747:2018, and luer connection per ISO 80369-7 were performed. The performances of all models of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device.
Materials	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	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	Different The subject device includes some different materials in comparison to the predicate device, but they are all materials largely used for other legally marketed devices under the same product code. The biocompatibility and performance testing shows that differences in materials of construction do not raise any questions of safety or effectiveness.
Biocompatibility	Meet requirements for ISO 10993-1	Meet requirements for ISO 10993-1	substantially equivalent
Sterilization	SAL 10^{-6}, Radiation	SAL 10^{-6}, Radiation	same
Reusable	No	No	same
Packing Pouch	Polyethylene (LDPE) for gamma sterilized bags	Polyethylene (LDPE) for gamma sterilized bags	same

The subject device and the predicate device have similar indications for use; the subject device is indicated for general fluids whereas the predicate device is indicated for TPN only: the Indications for Use (IFU) 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 IFU between the subject and the predicate device 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. EVA is a stable material generally used in the administration of IV solutions to patients in hospitals and pharmacies. Expanding the IFU from TPN to general use does not affect the safety and effectiveness of the device, as supported by Biocompatibility per ISO 10993-1, chemical and performance testing per ISO 15747:2018, and luer connection per ISO 80369-.

The materials used to manufacture the subject device are the same or similar to those used for the predicate device. The subject device includes additional materials in comparison to the predicate device; however, these differences do not raise new questions of safety and effectiveness as they have been assessed through biocompatibility testing.
The subject device with the 3-tube configuration has the same technological characteristics and design as the predicate device. The subject device also has a 1-tube configuration, where the filling of the bag and the administration of the solution to the patient are performed in the

same tube, this different design does not affect the basic design principle and usage of the subject device and does not raise additional safety and effectiveness issue compared to the predicate device.

SUBSTANTIAL EQUIVALENCE DISCUSSION:

DISCUSSION OF NONCLINICAL TESTS

Nonclinical 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 similar to those used for the predicate device. All the materials used to manufacture the subject device are largely used for other legally marketed devices under the same product code.

Biocompatibility has been tested according to the requirements of
- 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, Tests for in vitro cytotoxicity;*
- Sensitization and Intracutaneous Reactivity, *ISO 10993-10: 2010 Biological evaluation of medical devices, Tests for irritation and skin sensitization*;
- Acute Systemic Toxicity, *ISO 10993-11:2017 Biological evaluation of medical devices, Tests for systemic toxicity;*
- Subchronic Systemic Toxicity, *ISO 10993-11:2017 Biological evaluation of medical devices, Tests for systemic toxicity;*
- Material-Mediated Pyrogenicity, *USP 43 <151>;*
- Bacterial Endotoxin (LAL test), *USP 42 NF 37;*
- Hemolysis direct and indirect, *ISO 10993-4: 2017 Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood, ASTM F756-17*

The subject device meets requirements for ISO 10993-1 as the predicate device.

Performance tests:
The following non-clinical tests were performed to confirm that differences in materials and technological characteristics do not affect the safety or effectiveness of the device:
- ISO 15747:2018 *Plastic containers for intravenous injections*
  - Resistance to temperature, pressure and leakage
  - Resistance to leakage in storage
  - Resistance to dropping
  - Transparency

- Cover
- Penetration ability of the insertion port
- Adhesion strength of the infusion device and impermeability of the insertion port
- Tightness of the injection point
- Tensile strength of the hanger
- Identification legibility
- Resistance to hot printing removal
- Hydraulic seal and mechanical resistance of the non-re-opening clamp
- Pneumatic seal of the pinch (on/off) clamp and tubing/clamp damage
- Pinch (on/off) clamp flow rate
- UV transmission
- Mechanical resistance of bonding (tensile strength)
- Impermeability for microorganisms
- Luer Connection, *ISO 80369-7, Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*
- Filling test
- Visible Particulates in Injections according to USP <790>
- Particulate matter according to USP <788> Particulate Matter in Injections (Method 1)

The package integrity was tested according to:

- ISO 11607-1:2019 *Packaging for terminally sterilized medical devices – Requirements for materials, sterile barrier systems and packaging systems*
- ASTM D4332-01 (2006) *Standard Practice for Conditioning Containers, Packages, or Packaging Component for Testing*
- ASTM D4169-16 *Standard Practice for Performance Testing of Shipping Containers and Systems*
- ASTM F1980-02 *Standard Guide for Accelerated Aging of Sterile Medical Device Packages*

Chemical testing according to:

- ISO 15747:2018 *Plastic containers for intravenous injections*
- USP <643>

The following tests were performed:

- Requirements for the raw container or the sheeting (Sulphated ashes)
- Requirements for the test fluid
- Identification by FT-IR spectrometry Total organic carbon (TOC)
- DEHP (Di(2-ethylhexyl) phthalate) analysis quantification

CONCLUSION:

All the necessary safety and performance tests in support of substantial equivalence determination were conducted. The tests demonstrate that the subject Empty EVA Bag is substantially equivalent to the predicate device with respect to the intended use, target populations, treatment method, and technological characteristics.. The minor differences between the devices do not raise any new issues of safety or effectiveness.