July 22, 2020

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

Re: K193528
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: June 26, 2020
Received: July 1, 2020

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,

for Payal Patel
Acting 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K193528

Device Name
Empty EVA Bag

Indications for Use *(Describe)*
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.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary - K193528


| | |
|---|---|
| Company Name: | Haemotronic S.p.a. |
| Company Address: | Via Carreri 16<br>41037 – Mirandola (Modena)<br>Italy |
| Company Phone: | +39 0535 619611 |
| Company Fax: | +39 0535 619619 |
| Company e-mail: | E-mail: regulatory@haemotronic.it |
| Official Contact for Correspondence: | Franciosi Paola - QA Manager<br>Haemotronic S.p.a. |
| Phone: | +39 0535 619632 |
| E-mail: | E-mail: regulatory@haemotronic.it |


Date Summary Prepared: June 25, 2020

DEVICE IDENTIFICATION

| | |
|---|---|
| Trade name: | Empty EVA Bag |
| Generic/ Common Name: | empty I.V. bag |
| Regulation number: | 21 CFR §880.5025<br>Class II |
| Regulation name: | I.V. container. |
| Product Code: | KPE |
| Panel: | General Hospital |

PREDICATE DEVICES:

Empty EVA Solution Container, Acta Medical, K121161

DEVICE DESCRIPTION:

The device is an empty flexible container (bag) in EVA material (Ethylene-vinyl acetate), that is to be filled up before use and intended for the administration of intravenous infusion solutions (TPN-Total Parenteral Nutrition). The bag is provided with three tubes necessary for the filling of the bag itself and the administration of the solution to the patient. The empty bag is filled by connecting it to containers (generally glass bottles) containing one or more solutions. The filling is done by the tube with the big bore connector where the non-re-opening clamp is located. After filling, the bag is clamped by means of non-re-opening clamp ad 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 already filled, other medications can be added using the second access port (injection port). The device will be available in multiple containment volumes ranging from 250mL to 5000mL.

INDICATIONS FOR USE:

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.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

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

| Feature | EMPTY EVA BAG (Submitted Product) | PREDICATE DEVICE | CONCLUSION |
|---|---|---|---|
| K number | K193528 | K121161 | |
| Proprietary / Trade Name | Empty EVA Bag | Empty EVA Solution Container | |
| Manufacturer | HAEMOTRONIC S.p.a.. | ACTA MEDICAL | |
| CFR Section | 880.5025 | 880.5025 | substantially equivalent |
| Product code | KPE | KPE | substantially equivalent |
| Classification name | I.V. Container, General Hospital | I.V. Container, General Hospital | substantially equivalent |
| Indications for Use / Intended Use | 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. | An Empty Container with sterile fluid pathway used to store intravenous solution for administration to patient. Medication transfer in and out of the container is done using aseptic technique | The subject device and the predicate device have a similar intended use; the subject device has a narrower intended use in comparison to the predicate device: the specific solution (TPN) proposed for the intended use of the subject device is included in the more general indications stated for the predicate device ('intravenous solution'). This change of the subject device into a specific use (TPN only) does not affect the safety and effectiveness of the subject device, as proved by the tests performed on the subject device. |
| Design | 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. | Empty EVA Solution Container has a fill port to fill the container, injection port for additions of injectable additives and a spike port to connect intravascular administration tubing. The fill port tubing has a sealing clamp to secure the contents during storage post filling and prior to their administration. | The subject device is similar in design to the predicate device (single chamber), with fill port, injection port for additional medications, spike port for administration and inviolable clamp to be used after filling the bag. The subject device and the reference device have the same design. |
| Materials | EVA (Ethylene-vinyl acetate)<br>PVC (Polyvinyl Chloride)<br>ABS (Acrylonitrile butadiene styrene)<br>PP (Polypropylene)<br>SBC (Styrene Butadiene Copolymer)<br>MABS (Methyl Methacrylate Acrylonitrile Butadiene Styrene)<br>Thermoplastic Elastomer | EVA,<br>ABS,<br>Silicone | substantially equivalent<br>The subject device includes additional materials in comparison to the predicate device, but they are all materials largely used for other legally marketed devices under the same product code.<br>The biocompatibility and performance testing show 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 | substantially equivalent |
| Packing Pouch | Polyethylene (LDPE) for gamma sterilized bags | Polyethylene terephthalate (PET)/ paper | similar;<br>the minor difference in the material of the pouches does not impact on safety and effectiveness of the device, as the Sterility assurance level is 10-6, the same compared to the predicate device. |

The subject device and the predicate device have the same intended use. The indication for use of subject device is narrower and included in the indications for use of predicate device. The narrower indication for use of the subject device, which is within the scope of the predicate, does not raise any additional questions of safety and effectiveness.

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, but they are all materials largely used for other legally marketed devices under the same product code as the submitted Empty EVA bags.
Both the devices are comprised of ethylene vinyl acetate (EVA) which is a well know material used in the manufacturing of I.V. container bags, typically these types of bags are used for Total Parental Nutrition (TPN).

The subject device is similar in technological characteristics and design to the predicate device (in the single chamber configuration): 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 use of the subject device is limited to less than 24 hours and it is intended for qualified staff only, just as 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 the same/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: 2009 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;
- Haemolysis direct and indirect, ISO 10993-4:2009 "Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood"
- Subacute/sub- chronic systemic toxicity according to ISO 10993-11" Biological evaluation of medical devices, Test for systemic toxicity"

Pyrogenicity- Material Mediated/Bacterial Mediated

Performance tests:

According to

-ISO 15747:2018 'Plastic containers for intravenous injections'
- Bag Volume Capacity (per internal specification),
- Resistance to hot printing removal (per internal specification),
- Hangar Tensile Force – Internal Specification
- Hydraulic seal and mechanical resistance of the non-re-opening clamp (per internal specification),
- Particulate matter according to USP<788> Particulate Matter in Injection (Method 1)

Sterility:

Gamma Radiation per ISO 11137-1:2006 " Sterilization of health care products- Radiation- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO11137-2:2013" Sterilization of healthcare products- Radiation- Part 2: Establishing the sterilization dose

The package integrity was tested according to:

- ISO 11607-1:2019 "Packaging for terminally sterilized medica devices – Requirements for materials, sterile barrier systems and packaging systems"

CONCLUSION:

All the necessary safety and performance tests in support of substantial equivalence to the predicate device were conducted. The minor differences between the devices do not raise any new questions of safety or effectiveness.