K101412

APR 13 2011

510 (k) Summary of safety and effectiveness

SUBMITTER INFORMATION

A.	Company Name:	Valmed s.r.l.
B.	Company Address:	Via Provinciale, 10 Mazzo di Valtellina (SO), Italy 23030
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D.	Contact Person:	Walter Svanosio QA Manager Valmed s.r.l. E-mail: aq@valmedsrl.com
E.	Date Summary Prepared:	March 14, 2011

DEVICE IDENTIFICATION

A.	Device name:	EVA TPN bag
B.	Trade/Proprietary Name:	EVA TPN bag
C.	Classification name:	I.V. Container, General Hospital (21 CFR §880.5025)
D.	Product Code:	KPE

LEGALLY MARKETED DEVICES (PREDICATE DEVICES)

- B.BRAUN MEDICAL INC.: EVA TPN Container, K041415
- BAXTER HEALTHCARE CORPORATION: ALL-IN-ONE CONTAINER, K090096, K983294

DEVICE DESCRIPTION

The EVA TPN bags are empty containers for use in compounding and storage of sterile medical solutions such as parenteral nutrition solutions prior to and during administration to a patient using an intravascular administration set.

The empty bags are filled by connecting them to containers through standard spikes .A transfer set in different configurations, ranging from one-lead to three-lead sets, can be provided with the empty bag. The bags are clamped after filling by means of non-reopening clamps. Additional medications can be added to the container using a medication port. After filling, the containers can be attached to an intravascular administration set via the set port. The bags range in volume capacity from 150 mL to 5000 mL. The bag is discarded after use

The EVA TPN bags are made of a copolymer of ethylene and vinyl acetate. The tubings of the transfer set are made of a polyvinyl chloride material.

INTENDED USE

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.

SUBSTANTIAL EQUIVALENCE

Following comparison chart summarizes the technological characteristics of the Eva TPN bags compared with those of the predicate devices:

ATTRIBUTE / CHARACTERISTICS	EVA TPN bag (Submitted Product)	LEGALLY MARKETED PREDICATE DEVICES OF B. Braun Medical Inc.	LEGALLY MARKETED PREDICATE DEVICES OF Baxter Healthcare Corporation
"K" numbers	K_____	K041415	K090096, K983294
Proprietary / Trade Name		EVA TPN Container	All-In-One Container
CFR Section	880.5025	SAME	SAME
Pro-code	KPE	SAME	SAME
Classification name	I.V. container	SAME	SAME
Intended / Indications For Use	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 EVA TPN container 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 All-In-One Container is intended for use in the compounding and storage of parenteral nutrition solutions prior to and during intravascular administration to a patient.

ATTRIBUTE / CHARACTERISTICS	EVA TPN bag (Submitted Product)	LEGALLY MARKETED PREDICATE DEVICES OF B. Braun Medical Inc.	LEGALLY MARKETED PREDICATE DEVICES OF Baxter Healthcare Corporation
"K" numbers	K_____	K041415	K090096, K983294
Description	Bags are made of Ethylene vinyl acetate (EVA) to preserve the stability of fat in the nutritional blend longer. The presentations are available in volume capacity from 150ml to 5000ml	Ethylene vinyl acetate (EVA) is a suitable material to preserve the stability of fat in the nutritional blend longer. The bags for the preparation of PN B Braun sold in USA are manufactured in EVA and presentations are available in volume capacity from 250ml to 4000ml.	Ethylene vinyl acetate (EVA) is a suitable material to preserve the stability of fat in the nutritional blend longer. The bags for the preparation of PN Baxter sold in USA are manufactured in EVA and presentations are available for up to 1L, 2L, 3L and 4L.
Bag material	EVA, phthalate-free ethyl vinyl acetate plastic	EVA, phthalate-free ethyl vinyl acetate plastic	EVA, phthalate-free ethyl vinyl acetate plastic
Connector	Plastic, no components made of natural rubber latex (use of isoprene).	Plastic, no components made of natural rubber latex (isoprene).	Plastic, no components made of natural rubber latex (use of isoprene).
Injection site	Plastic, no components made of natural rubber latex (use of isoprene).	Plastic, no components made of natural rubber latex (isoprene).	Plastic, no components made of natural rubber latex (use of isoprene).
Tubing material	PVC with DEHP plasticizer DEHP FREE PVC	PVC with DEHP plasticizer DEHP FREE PVC	PVC
Transfer set	Three lead transfer set, single lead transfer set	Three lead transfer set	Three lead transfer set, single lead transfer set
Medication port	Yes	Yes	Yes
Biocompatible	Yes	Yes	Yes
Sterility	SAL 10^{-6}, ETO	SAL 10^{-6}	SAL 10^{-6}
Single-use	Yes	Yes	Yes

Materials and intended use of the EVA TPN bags and the predicate devices are essentially the same. Design is similar, depending on the various models and options. Valmed believes that there are no differences between the submitted product and the legally marketed predicate devices that arise issues of safety and effectiveness.

Based on the available 510(k) summaries, the marketing literature and the information provided herein, Valmed concludes that the EVA TPN bags are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act.

NON CLINICAL TESTS SUMMARY

Biological, chemical and physical testing performed on the final product demonstrate that the device fulfills the requirements set out in International Standard ISO 15747:2003 Plastics containers for intravenous injection.

Functional testing showed correct operation of the device.

CONCLUSIONS

Results of the non clinical and bench tests performed demonstrate safety and effectiveness of the devices. Based on the results of the testing performed, Valmed believes that the device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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ITALY 123030

Re: K101412
Trade/Device Name: EVA TPN Bags
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. Container
Regulatory Class: II
Product Code: KPE
Dated: March 21, 2011
Received: March 25, 2011

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Dear Mr. Svanosio:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K101412

Device Name: EVA TPN bags

Indications for Use:

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. .

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

4/13/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K101412