K130867

JUN 14 2013

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	March 26, 2013
Submitter:	Vital Signs Inc., A GE Healthcare Company 20 Campus Road Totowa, NJ 07512 Telephone: (973) 597-1800
Primary Contact Person:	Stacie Geffner-Atiya Regulatory Affairs Manager Vital Signs Inc., A GE Healthcare Company Telephone: (973) 956-5491 Fax: (973) 956-5442 Email: stacie.geffner-atiya@ge.com
Secondary Contact Person:	Trishia Dwyer Regulatory Affairs Leader GE Healthcare Telephone: (608) 221-1551 x500-3074 Fax: (608) 646-6488 Email: trishia.l.dwyer@ge.com
Device Trade Name:	enFlow IV Fluid Warmer, enFlow IV Fluid Warmer Insulated Strap
Common/Usual Name:	enFlow, Insulated strap, i-strap
Classification Names: Product Code:	Warmer, Thermal, Infusion Fluid LGZ BSB - 21 CFR 864.9205
Predicate Device(s):	K121775, enFlow IV Fluid Warmer Strap

Device Description:	The Insulated Strap is an accessory to the enFlow IV Fluid Warmer which is used to secure the warmer component of the enFlow IV Fluid Warmer System to the patient during transport. The Insulated strap consists of a silicone strap, an insulating element and a mounting plate, into which the user can secure the enFlow IV Fluid Warmer.
Intended Use:	The enFlow IV Fluid Warmer System is indicated for warming blood, blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia.
Technology:	The enFlow IV Fluid Warmer with Insulated Strap accessory does not change the fundamental scientific technology of the enFlow IV Fluid Warmer with Strap, its predicate device. The Insulated Strap is equivalent in performance to the predicate strap, but introduces new materials which compose the insulating element and the mounting plate.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> The enFlow IV Fluid Warmer with Insulated Strap and its accessories comply with voluntary standards. The following quality assurance measures were applied to the development of the system: ▪ Risk Analysis - Risk Management was employed throughout the development and implementation of the enFlow IV Fluid Warmer System. ▪ Design & Performance Verification Testing including functional, packaging and labeling evaluations - verified that the enFlow Fluid Warmer IV System meets the defined specifications. ▪ Biocompatibility testing - The materials used in the Insulated strap meet the biocompatibility requirements per ISO 10993. ▪ User Validation Testing – User testing was performed to validate the enFlow IV Fluid Warmer Insulated Strap against its intended use. <u>Summary of Clinical Tests:</u> The subject of this premarket submission, enFlow IV Fluid Warmer Insulated Strap, did not require clinical studies to support substantial equivalence.

Conclusion:	GE Healthcare considers the enFlow IV Fluid Warmer System with the Insulated Strap to be as safe, as effective, and to perform in a substantially equivalent manner to the current enFlow IV Fluid Warmer System, and to the predicate device enFlow IV Fluid Warmer Strap.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 14, 2013

Vital Signs, Incorporated, A GE Healthcare Company
Ms. Stacie Geffner-Atiya
Regulatory Affairs Manager
20 Campus Road
TOTOWA NJ 07512-1210

Re: K130867
Trade/Device Name: enFlow IV Fluid Warmer
Regulation Number: 21 CFR 864.9205
Regulation Name: Blood and Plasma Warming Device
Regulatory Class: Unclassified
Product Code: LGZ
Dated: May 24, 2013
Received: May 29, 2013

Dear Ms. Geffner-Atiya:

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 contact 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. 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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K130867

Device Name: enFlow IV Fluid Warmer

Indications for Use:

The enFlow IV Fluid Warmer is indicated for warming blood, blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia.

Prescription Use x AND/OR Over-The-Counter Use

(Part 21 CFR 801 Sub part D) (Part 21 CFR 801 Subpart C)

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FDA

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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