JAN 16 2014

K132528

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510(k) Summary

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

Owner/Contact/Date (807.92(a)(1):

Date:	August 10, 2013
Owner/Submitter:	GE Healthcare Finland Oy. Kuortaneenkatu 2 00510 Helsinki FINLAND Phone: +358 10 39411 Fax: +358 9 1463310
Primary Contact Person:	Joel Kent Manager, Quality and Regulatory Affairs GE Healthcare Phone: 781-449-8685 Fax: 781-433-1344 E-mail: joel.kent@ge.com
Secondary Contact Person:	Janne Marvola Regulatory Affairs Leader GE Healthcare Finland Oy Kuortaneenkatu 2 00510 Helsinki Finland Phone: + 358 10 394 2172 Fax: +358-92726532 E-mail: janne.marvola@ge.com

Device names (807.92(a)(2)):

Trade Name:	E-PiCCO Continuous Cardiac Output Module and accessories
Common/Usual Name:	Single-function, preprogrammed diagnostic computer
Classification Names:	21 CFR 870.1435 Single-function, preprogrammed diagnostic computer.
Product Code:	DXG

Predicate Device(s) (807.92(a)(3)::	K060898 Pulsion PiCCO Plus
Device Description (807.92(a)(4))::	The E-PiCCO Continuous Cardiac Output Module and accessories is a new, single width E-series plug-in parameter module for pulse contour continuous cardiac output (PCCO) measurement and associated parameters. E-PiCCO Continuous Cardiac Output Module and accessories uses interconnect cables for both for injected bolus temperature measurement and for continuous

cardiac output measurement. Patient access is via a clinician inserted arterial catheter, provided by Pulsion Medical Systems AG. The E-PiCCO Continuous Cardiac Output Module and accessories can be used with the CARESCAPE Monitor B850 with ESP V2 software, the CARESCAPE Monitor B650 with ESP V2 software and CARESCAPE Monitor B450 with ESP V2 software.

Intended Use: (807.92(a)(5):

Indications for use E-PiCCO Continuous Cardiac Output Module: The E-PiCCO is intended for determination and monitoring of cardiopulmonary and circulatory variables. Cardiac output is determined both continuously through pulse contour analysis and intermittently through thermodilution technique. In addition, the E-PiCCO measures systolic, and diastolic and derives mean arterial pressure. Analysis of thermodilution curve in terms of mean transit time and downslope time is used for determination of intravascular and extravascular fluid volumes. If a patient's weight and height are entered, the compatible patient monitor presents the derived parameters indexed to body surface area. The E-PiCCO is intended for hospitalized patients. The E-PiCCO and accessories are for use by qualified medical personnel only. The E-PiCCO patient module is intended for use on one patient at a time. Cardiac output measurement with E-PiCCO is intended for patients weighing over 2 kg (4.4 lb) and therefore it is not available for smaller patients. E-PiCCO indexed values are available for patients weighing over 15 kg (33 lb) only.

Indications for use PiCCO Continuous Cardiac Output Cable (M1154585): The reusable, continuous cardiac output adapter cables are intended to be used for connecting a continuous cardiac output catheter to GE Medical Systems Information Technologies monitoring equipment requiring a rectangular 11-pin connector cable. These accessories are indicated for use by qualified medical personnel only.

Indications for use PiCCO Injectate Sensor Cable (M1182448): The reusable PiCCO Injectate Sensor Cable (M1182448) is intended to be used for connecting the PiCCO Injectate Sensor Housing (PV4046) to PiCCO Continuous Cardiac Output Cable (M1154585) of GE Healthcare monitoring equipment. These accessories are indicated for use by qualified medical personnel only.

Technology (807.92(a)(6))::

The E-PiCCO Module measures the injectate temperature using a PiCCO Injectate Temperature Sensor Cable and blood temperature using a PiCCO catheter connected to the module using a PiCCO Continuous Cardiac Output Cable. The E-PiCCO Module measures invasive blood pressure using a generic invasive blood pressure transducer connected to the module using an invasive blood pressure cable.
The fundamental technology of the E-PiCCO Continuous Cardiac Output Module and accessories is the same as the predicate device.
The E-PiCCO Continuous Cardiac Output Module and accessories is as safe and effective the predicate device.

Determination of Substantial Equivalence (807.92(b)(1))::

Summary of Non-Clinical Tests:
The following quality assurance measures were applied to the development of the E-PiCCO Continuous Cardiac Output Module and accessories :

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

The E-PiCCO Continuous Cardiac Output Module and accessories were designed and tested for compliance to the following standards:

1. IEC 60601-1:1988, A1:1991, A2:1995, Corr1:1995, Medical Electrical Equipment Part 1: General Requirements for Safety – Second Edition
2. IEC 60601-1-1:2000, Medical Electrical Equipment - Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems – Edition 2.0
3. IEC 60601-1-2:2001 + A1:2004, Medical electrical equipment – Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility – Requirements and tests – Edition 2.1
4. IEC 60601-1-4:1996 + A1:1999 (AKA ed 1.1:2000), Medical electrical equipment - Part 1: General requirements for safety - 4 - Collateral standard: Programmable electrical medical systems, Edition 1.1

5. IEC60601-1-6:2006, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – collateral Standard: Usability – Edition 2
6. IEC 60601-1-8:2006, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems, Second Edition
7. IEC 60601-2-34:2000, Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment-Edition 2
8. IEC62304:2006, Medical device software - Software life cycle processes
9. IEC62366:2007, Medical Devices – Application of usability engineering to medical devices (General)

Clinical (807.92(b)(2)):

Summary of Clinical Tests:
The subject of this premarket submission, the E-PiCCO Continuous Cardiac Output Module and accessories did not require clinical studies to support substantial equivalence.

Conclusion (807.92(b)(3))::

GE Healthcare considers the E-PiCCO Continuous Cardiac Output Module and accessories to be as safe, as effective, and performance is substantially equivalent to the predicate device K060898 Pulsion PiCCO Plus.

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

January 16, 2014

GE Healthcare Finland Oy
c/o Mr. Joel Kent
86 Pilgrim Road
Needham, MA 02492

Re: K132528
Trade/Device Name: E-PiCCO Continuous Cardiac Output Module and accessories
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-function, preprogrammed diagnostic computer
Regulatory Class: Class II
Product Code: DXG
Dated: December 6, 2013
Received: December 9, 2013

Dear Mr. Kent:

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,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132528

Device Name: **E-PiCCO Continuous Cardiac Output Module and accessories**

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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)

Digitally signed by Owen P. Faris -S
Date: 2014.01.16 10:02:17 -05'00'