K093881

510(k) Summary

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

Date:	10-Feb-10
Submitter:	GE Healthcare Finland Oy Kuortaneenkatu 2 Helsinki FIN-00510 FINLAND
Primary Contact Person:	Tommi Jokiniemi RA Leader GE Healthcare +358-10-394 6561 +358-9-272 6532
Secondary Contact Person:	Päivi Roiha RA Leader GE Healthcare +358-10-394 6743 +358-9-272 6532
Device: Trade Name:	TruSignal® SpO2 Sensors and Interconnect Cables
Common/Usual Name:	Pulse Oximeter Sensors and Interconnect Cables
Classification Names:	21 CFR 870.2700, 21 CFR 870.2710
Product Code:	DQA, DPZ
Predicate Device(s):	K062576 S/5 E-PSM(P) Module and Accessories K040831 TruSat Pulse Oximeter and Accessories K021955 3800 Series and 3900 Series Oximeters and Accessories K992323 Cardiocap 5 and Accessories
Device Description:	Pulse oximeter sensors and interconnect cables connecting to patient monitors
Intended Use:	TS-F-D *The Finger Sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO_2) and pulse rate monitoring. Patient weight range > 20 kg (> 44 pounds)* TS-E-D *The Ear Sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO_2) and pulse rate monitoring. The headband is single-patient use. Patient weight range > 10 kg (> 22 pounds)* TS-W-D *The Wrap Sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. The tape and foam wrap are single-patient use. Patient weight range > 3 kg (> 6.6 pounds)* ***Contraindications*** *Sensitivity to adhesive tape may cause an allergic reaction.*

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TS-SE-3

The Sensitive Skin Sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. The tape and foam wrap are single-patient use. Patient weight range All patients

Contraindications

Sensitivity to adhesive tape may cause an allergic reaction.

TS-AF-10 and TS-AF-25

The AllFit Sensor is a single-patient use adhesive sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. Patient weight range All patients

Contraindications

Sensitivity to adhesive tape may cause an allergic reaction.

Trusignal SpO2 Interconnect cables

The Interconnect Cable is a reusable cable intended for use for all patients for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring when used with a compatible SpO2 sensor.

Intended use has not changed as a result of the modifications to the predicate devices.

Technology: The TruSignal® SpO2 Sensors and Interconnect Cables employ the same fundamental scientific technology (transmission based optical SpO2 measurement) as its predicate devices. The TruSignal® SpO2 Sensors and Interconnect Cables are identical to the predicate devices except for the cable materials and connector design. All optical components, materials, geometry and dimensions in the sensor heads are identical to the predicate devices..

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The TruSignal® SpO2 Sensors and Interconnect Cables and its applications comply with voluntary standards as detailed in Section 9 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Component verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

To support EMC, safety and bench testing in demonstrating the proposed devices are equivalent to the cleared predicated devices regarding safety and effectiveness a clinical verification test was performed on the proposed devices on an extensive selection of GE patient monitors.

The test consisted of induced hypoxia studies on ten healthy adult volunteers (ages 18-42 yr, 105-227 lbs, with light to dark pigmentation) during non-motion conditions conducted in an independent research laboratory. The measured arterial hemoglobin saturation values of the proposed devices were compared to a reference oximeter system whose readings were converted to Co-oximeter based arterial hemoglobin saturation values using empirical linear regression translation equation. Arterial blood samples were not taken for the subjects during the test for direct comparison with the arterial hemoglobin saturation readings of the proposed devices as the changes to the proposed devices compared to the predicate devices are not significant as defined in FDA's proposal in Pulse Oximeters – Premarket Notification Submissions [510(k)s] Draft Guidance July 19, 2007 Section 7.

All sensors were shown to have an A_RMS of less than 2 (except Ear sensors A_RMS of less than 3) during steady state conditions over the range of 70-100% which demonstrates the SpO2 measurement accuracy performance of the proposed devices having new cable and connector design is substantially equivalent to the predicate devices.

No adverse effects or complications were observed during the study.

The results of the Non-Clinical and Clinical tests do not raise any questions on the safety and effectiveness of the proposed devices.

Conclusion: GE Healthcare considers the TruSignal® SpO2 Sensors and Interconnect Cables to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Tommi Jokiniemi
GE Healthcare Finland OY
Kuortaneenkatu 2
Helsinki
Finland Fin-00510

MAR 12 2010

Re: K093881
Trade/Device Name: TruSignal® SpO2 Sensors and Interconnect Cables
Regulation Number: 21CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, DPZ
Dated: February 10, 2010
Received: February 16, 2010

Dear Mr. Jokiniemi:

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/ucm 115809.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,

for

Anthony D. 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

510(k) Number (if known):

Device Name: TruSignal® SpO2 Sensors and Interconnect Cables

Indications for Use:

TS-F-D
The Finger Sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO_2) and pulse rate monitoring. Patient weight range > 20 kg (> 44 pounds)

TS-E-D
The Ear Sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO_2) and pulse rate monitoring. The headband is single-patient use. Patient weight range > 10 kg (> 22 pounds)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K093881

510(k) Number (if known):

Device Name: TruSignal® SpO2 Sensors and Interconnect Cables

Indications for Use:

TS-W-D
The Wrap Sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. The tape and foam wrap are single-patient use. Patient weight range > 3 kg (> 6.6 pounds)
Contraindications
Sensitivity to adhesive tape may cause an allergic reaction.

TS-SE-3
The Sensitive Skin Sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. The tape and foam wrap are single-patient use. Patient weight range All patients
Contraindications
Sensitivity to adhesive tape may cause an allergic reaction.

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

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Infection Control, Dental Devices

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510(k) Number (if known):

Device Name: TruSignal® SpO2 Sensors and Interconnect Cables

Indications for Use:

TS-AF-10 and TS-AF-25
The AllFit Sensor is a single-patient use adhesive sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. Patient weight range All patients
Contraindications
Sensitivity to adhesive tape may cause an allergic reaction.

Trusignal SpO2 Interconnect cables
The Interconnect Cable is a reusable cable intended for use for all patients for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring when used with a compatible SpO2 sensor.

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

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