K083787

APR 15 2009

510(k) Summary of Safety and Effectiveness

Manufacturer:	Smiths Medical
Address:	N7 W22025 Johnson Drive Waukesha, WI 53186
Telephone Number:	(262) 542-3100
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Contact Person:	Donald Alexander Director Regulatory Affairs
Date Prepared:	December 1, 2008
Proprietary Name:	BCI® model WW1000 Pulse Oximeter
Common/Classification Name:	Pulse Oximeter
Product Code:	DQA
Regulation Number:	870.2700 (Class II)
Predicate Devices:	Masimo SET Radical pulse oximeter (K040214) BCI® Autocorr model 3304 pulse oximeter (K070732) BCI® MiniCorr model 3402 pulse oximeter (K991410)

Device Description:

The aim of this submission is to obtain market clearance for the BCI model WW1000 pulse oximeter.

The BCI® model WW1000 handheld pulse oximeter is intended for spot-check applications. The WW1000 monitors and displays patient functional oxygen saturation (%SpO_2), pulse rate, pulse amplitude index, and pulse signal strength information. It does not have audible or visual patient alarms. The user interface includes a red LED display and an ON/OFF button.

The WW1000 comes with disposable AA batteries, the 3044S reusable pulse oximetry sensor and relevant manuals. Optional accessories include other oximetry sensors, docking station, thermal printer (attaches to dock), rechargeable battery pack, universal mains AC charger, patient isolated USB cable, universal mounting bracket and protective glove. The WW1000 is compatible with BCI® oximetry sensors and extension cables.

Indications for Use

The BCI® model WW1000 handheld pulse oximeter is intended for spot-checking applications (non-continuous use). It monitors and displays a patient's functional oxygen saturation (%SpO_2), pulse rate, pulse signal strength, and pulse amplitude index readings. It may be used by physicians, respiratory therapists, nurses, certified nurse assistants, emergency medical technicians, sleep technicians, clinicians, and home users. The intended patient population ranges from infant to adult. It can be used on patients with low perfusion. The WW1000 may be used in the hospital or clinical environment, during emergency land transport, and in the home.

Risk Mitigation Table

Below is a summary of risks common to pulse oximeters and how this submission addresses those risks.

Identified Risk	**Mitigation Measures**
Inadequate Device Performance	Accuracy Testing (Section 11) Benchtop Performance Testing (Section 9) Software Documentation and Testing (Section 8)
Electrical or Mechanical Failure	Electrical, Mechanical, and Environmental Testing (Section 9)
Electromagnetic Interference	Electromagnetic Compatibility Testing (Section 9)
Adverse Tissue Reactivity	Biocompatibility Information (Section 10)
Cross-contamination or Infection	Cleaning and Disinfection Testing (Section 9)
Improper Use	Labeling (Section 7)

An in-depth risk management analysis, including mitigation measures, was performed on the BCI WW1000 system. The results are provided under Section 5.

Performance Testing

The BCI WW1000 pulse oximeter passed all performance bench top testing including EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity. Test reports, including test protocols, pass/fail criteria, results and conclusions, are provided under Section 9.

Clinical Testing

The WW1000 pulse oximeter utilizes an existing oximeter daughter-board (Micro-power OEM board 31392B1) that provides the complete measurement of SpO2 and Pulse Rate (PR) and digitally transmits the calculated values to a host device. The 31392B2 oximeter daughter-board underwent three clinical desaturation studies; two trials (Desat 24 and Desat 27) used the Micro-power OEM Board Evaluation kit (3375) with additional opto-isolation of the communication signals, and one (Desat 40) used the OxiLink-I host device which provides signal isolation.

Comparison testing among the Evaluation Kit (3375), OxiLink-I and WW1000 host devices was performed to demonstrate that all three systems produce the same readings under identical simulator settings. Results indicate that the Micro-power OEM board produced the same readings (within ±1 digit) in all three host devices.

The 31392B1 oximeter board underwent clinical desaturation study Desat 24 in July 2002 and Desat 27 in September 2003. In 2007/2008, hardware and software enhancements were made to the 31392B1 board to extend its operation over a wider range of perfusion index values and improve lower perfusion performance. Desat 40 was performed with the intent of verifying that these enhancements did not adversely affect SpO2 accuracy.

Results of the three individual clinical desaturation trials indicate that the WW1000 pulse oximeter performs as intended and is safe and effective for use. Please find complete desaturation test reports for Desat 24, 27 and 40 and applicable project file memos in Section 11.

Conclusion

Supporting information per this premarket submission confirms that the BCI® WW1000 pulse oximeter is substantially equivalent to its predicate devices.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2009

Mr. Donald Alexander
Director, Regulatory Affairs
Smiths Medical PM, Incorporated
N7 W22025 Johnson Drive
Waukesha, Wisconsin 53186-1856

Re: K083787
Trade/Device Name: BCI® Model WW1000 Pulse Oximeter
Regulation Number: 21 CFR 880.2700
Regulatory Class: II
Product Code: DQA, DPZ
Dated: March 26, 2009
Received: March 30, 2009

Dear Mr. Alexander:

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting 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): _____

Device Name: BCI® Model WW1000 Pulse Oximeter

Indications for Use:

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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)

Susan Runner

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

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