

K08 3357

## 510(k) Summary of Safety and Effectiveness

Manufacturer: Smiths Medical  
Address: N7 W22025 Johnson Drive  
Waukesha, WI 53186  
Telephone Number: (262) 542-3100  
Fax Number: (262) 542-3325  
Contact Person: Donald Alexander  
Director Regulatory Affairs  
Date Prepared: December 1, 2008  
Proprietary Name: BCI® model WW1030 Handheld 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)

MAY - 1 2009

### Device Description:

The aim of this submission is to obtain market clearance for the BCI model WW1030 pulse oximeter.

The BCI model WW1030 is a handheld pulse oximeter intended for continuous monitoring. The WW1030 monitors and displays patient functional oxygen saturation %SpO<sub>2</sub>, pulse rate, perfusion index, and pulse signal strength information. It is equipped with audible and visual patient alarms. The user interface includes a blue LED display, speaker, a 5-button keypad control, and an ON/OFF button.

The WW1030 comes with disposable batteries, a reusable pulse oximetry sensor with extension cable 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, nurse call cables, universal mounting bracket and protective glove. The WW1030 is compatible with BCI oximetry sensors, Nellcor DS100A oximetry sensor and extension cables.

### Indications for Use

The BCI® model WW1030 handheld pulse oximeter is intended to be used for continuous monitoring of a patient's functional oxygen saturation (%SpO<sub>2</sub>), pulse rate, pulse signal strength, and perfusion index readings. It is equipped with audible and visual alarms. 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 neonatal to adult. It can be used on patients with

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low perfusion or during patient motion. The WW1030 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.

| <b>Identified Risk</b>           | <b>Mitigation Measures</b>   |
|----------------------------------|--|
| Inadequate Device Performance    | Accuracy Testing (Section 9)<br>Benchtop Performance Testing (Section 9)<br>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 WW1030 system. The results are provided under Section 5.

### Performance Testing

The BCI WW1030 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 Digital Micro Power OEM oximeter board (31402B2) is a satellite board capable of monitoring a patient's SpO2 level, pulse rate and plethysmogram waveform. The Digital Micro Power OEM oximeter board is the pulse oximetry board in the BCI WW1030 pulse oximeter. This board has undergone three separate desaturation clinical studies: Desat 37, Desat 38, and Desat 39. The intent of the Desat Studies 37 and 38 was to determine the SpO2 accuracy of the pulse oximeter module using various sensors over the range 70-100% SaO2 as determined by the reference CO-oximeter. The intent of Desat Study 39 was to obtain clinical data to determine the SpO2 accuracy over the range 70-100% SaO2 as determined by a reference CO-oximeter under controlled motion conditions.

## Conclusion

Supporting information per this premarket submission confirms that the BCI® WW1030 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

MAY - 1 2009

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

Re: K083557

Trade/Device Name: BCI® Model WW1030 Pulse Oximeter  
Regulation Number: 21 CFR 870.2700  
Regulation Name: Oximeter  
Regulatory Class: II  
Product Code: DQA  
Dated: December 1, 2008  
Received: December 2, 2008

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.

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

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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

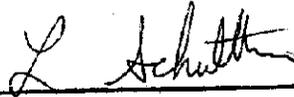
Enclosure

# Indications for Use

510(k) Number: K083557

Device Name: BCI Model® WW1030 Handheld Pulse Oximeter

Indications for Use: The BCI® Model WW1030 pulse oximeter is intended to be used for continuous monitoring of a patient's functional oxygen saturation (%SpO<sub>2</sub>), pulse rate, pulse signal strength, and pulse amplitude index readings. It is equipped with audible and visual alarms. It may be used by physicians, respiratory therapists, nurses, certified nurse assistants, emergency medical technicians, sleep technicians, clinicians and home use. The intended patient population ranges from neonatal to adult. It can be used on patients with low perfusion or during patient motion. The WW 1030 may be used in the hospital or clinical environment, during emergency land transport, and the home.



(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K083557

Prescription Use XXX  
(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 IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)