K980714

MAR 25 1998

Summary of Safety and Effectiveness

Submitter:	BCI International, Inc.
Address:	W238 N1650 Rockwood Drive Waukesha, WI 53188
Telephone:	(414) 542-3100
Contact:	VP Regulatory Affairs
Prepared:	February 20, 1998
Proprietary Name:	3401 Handheld Pulse Oximeter
Common/Classification Name:	Pulse Oximeter
Predicate Devices:	BCI 3301 Handheld Pulse Oximeter

New Device Description:

The BCI 3401 Handheld Pulse Oximeter is an updated version of an existing pulse oximeter legally marketed by BCI International. The system consists of two major elements. The first is the oximeter featuring the oximeter sensor interface, the LED display, and the keypad. The second element is the optional internal printer. The device is powered by four "AA" batteries.

Intended Use:

The BCI 3401 Pulse Oximeter is a handheld, low cost monitor for spot checking or attended monitoring of SpO_2, pulse rate and pulse strength. The 3401 is a battery powered pulse oximeter with an optional built-in printer. It may be used in the hospital or clinical environment, and during emergency land transport. The oximeter will operate accurately over an ambient temperature range of 32 to 131°F (0 to 55°C). The oximeter works with all BCI oximetry sensors providing SpO_2 and pulse rate on all patients from neonate to adult.

Performance Data:

The design of this device utilizes currently available technology found in many legally marketed devices. Testing was done to ensure that it would perform within the environment(s) for which it is to be marketed. The testing was performed in accordance with the guidelines and standards found in the reviewers guide for respiratory devices. This testing included EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity. The results of the testing demonstrated that the device was in compliance with the guidelines and standards referenced in the reviewers guide and that it performed within its specifications and functional requirements.

Additionally, clinically controlled desaturation studies were done to demonstrate that the 3401 accurately displays the patient's blood oxygen level within its accuracy limits as compared to a co-oximeter (OSM-3). Statistical analysis on the data collected from the studies were compared to those from a co-oximeter during the controlled subject desaturation runs. The results from the clinical studies support the accuracy claims of the device, with a standard deviation of 1.97 for the measurement range of 70-100%. The R squared value was 0.96 over the entire range. (R squared - measure of how true the regression line is. R squared = 1 is a perfect fit.) On the basis of these results and the above-referenced testing it is our determination that the device is safe, effective, and performs as well as the legally marketed predicate device.

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.

Respectfully,

Donald Alexander

Donald Alexander
VP Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 1998

Mr. Donald J. Alexander
BCI International
W238 N1650 Rockwood Drive
Waukesha, WI 53188-1199

Re: K980714
BCI 3401 Handheld Pulse Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: February 20, 1998
Received: February 24, 1998

Dear Mr. Alexander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if Known): K980714

Device Name: BCI 3401 Handheld Pulse Oximeter

Indications For Use:

Intended Use

The BCI 3401 Pulse Oximeter is a handheld, low cost monitor for spot checking or attended monitoring of SpO_2, pulse rate and pulse strength. The 3401 is a battery powered pulse oximeter with an optional built-in printer. It may be used in the hospital or clinical environment, and during emergency land. The oximeter will operate accurately over an ambient temperature range of 32 to 131°F (0 to 55°C). The oximeter works with all BCI oximetry sensors providing SpO_2 and pulse rate on all patients from neonate to adult.

This device is not intended for continuous patient monitoring. There are no audible or visable patient alarms. The device is not intended for home use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The_Counter Use _____
(Per 21 CFR 801.109)

3/24/98

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices