JUN 9 1999

K991410

Summary of Safety and Effectiveness

Submitter:	BCI International, Inc.
Address:	N7 W22025 Johnson Road Waukesha, WI 53186
Telephone:	(414) 542-3100
Contact:	VP Regulatory Affairs
Prepared:	April 5, 1999
Proprietary Name:	BCI Digital Handheld Oximeter (model 3402)
Common/Classification Name:	Pulse Oximeter
Predicate Devices:	BCI 3304 Pulse Oximeter (K962156) BCI 3401 Handheld Oximeter (K980714)

New Device Description:

The BCI 3402 Digital Handheld Oximeter monitor is an updated version of an existing pulse oximeter legally marketed by BCI International. The system consists of an oximeter sensor interface, LED display, front and side keypads, and an infra-red LED printer output port. The device is powered by six "AA" batteries.

Intended Use:

The BCI 3402 Digital Hand Held Oximeter will be an enhanced, low cost Oximeter used for spot checking or monitoring of patients SpO_2 and pulse rate. The 3402 is a battery powered pulse oximeter with a built in infra-red printer output port. The device will provide fast, reliable measurements on patients ranging from neonates to adults when using the appropriate BCI SpO_2 sensors. The device is intended for use in both clinical and EMS environments by health care professionals, in sleep screening and in the home.
The BCI 3402 is not designed or intended to be used as an apnea monitor.

Performance Data:

The design of this device utilizes currently available technology found in many legally marketed devices. Testing was done previously to ensure that the BCI 3402 monitor 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 reviewer's guides for respiratory

devices. Electromagnetic compatability (EMC), electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing has been completed. The results demonstrated that the BCI 3402 monitor was in compliance with the guidelines and standards referenced in the reviewer's guides and that it performed within its specifications and functional requirements.

Additionally, clinically controlled desaturation studies were done to demonstrate that the 3402 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 1.49 for the measurement range of 70-100%. The R squared value was 0.98 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(s).

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
VP Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 9 1999

Mr. Donald J. Alexander
BCI International
N7 W22025 Johnson Road
Waukesha, WI 53186

Re: K991410
BCI 3402 Handheld Pulse Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: April 20, 1999
Received: April 22, 1999

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 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). 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/dsma/dsmamain.html".

Sincerely yours,

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): K991410

Device Name: BCI Digital Handheld Pulse Oximeter. Model 3402, Pulse Oximeter.

Indications For Use:

Intended Use:

The 3402 Digital Handheld Oximeter is a handheld, low cost pulse oximeter for spot checking or continuous monitoring of SpO_2, pulse rate, and pulse strength. It may be used in all critical environments, including clinical and EMS (Emergency Medical Services), patient ground transport, and for use in sleep screening or in the home. The oximetry parameter works with all BCI oximetry sensors, providing SpO_2 and pulse rate on all patients from neonate to adult. The 3402 Digital Handheld Oximeter permits continuous patient monitoring with adjustable alarm limits as well as visual and auditory alarm signals.

The BCI 3402 is not designed or intended to be used as an apnea monitor.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Arthur A. Gierlowski

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

510(k) Number _____

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