AUG 20 1998

K981939

BCI INTERNATIONAL

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:	May 29, 1998
Proprietary Name:	BCI 3404 Oximeter / ECG Monitor
Common/Classification Name:	Pulse Oximeter
Predicate Devices:	BCI 3304 Pulse Oximeter BCI 3100 Oximeter / ECG Monitor Siemens SC6000 Bedside Monitor

New Device Description:

The BCI 3404 Oximeter / ECG Monitor is a new monitor with the same parameters as existing devices legally marketed by BCI International. This device is designed to provide full featured monitoring capabilities in a table top design. The system features an ECG cable interface, an SpO_2 probe interface, display of patient and waveform data via an EL panel, power status LED, and the function keypad area consisting of six keys (on/off, waveform / trend, alarm silence, menu / enter, up arrow & down arrow). The monitor has a serial port that is used for data communications to a printer or computer and for analog outputs.

Intended Use:

The BCI 3404 Monitor is a portable ECG and oximetry monitor with optional impedance respiration. It continuously and non-invasively monitors and displays functional oxygen saturation of arterial hemoglobin(SpO_2), pulse rate, respiration rate, plethysmogram and ECG waveforms. Alarms are available for ECG and oximetry. There are no respiration rate alarms. The 3404 may be used in the hospital or clinical environment, and during emergency land transport. The device will provide fast, reliable measurements on patients ranging from pediatric to adult when using the appropriate BCI accessories.

The monitor is not intended for home use. The monitor is not intended to be an apnea monitor. It was not designed or validated for use as an apnea monitor. The monitor is not intended for neonatal use.

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 found in the reviewers guide for respiratory devices and with international safety standards. 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.

Performance testing of the 3404 Monitor and its components were seperated into three types of testing. Bench tests using simulators were used to test each parameter. Clinical tests using volunteers were used to verify performance for respiration and oximetry. A performance standard was used for ECG (ANSI/AAMI EC13).

Bench Tests:

Three devices were tested on simulators to determine performance over the specified range. All of the simulators are commercially available. The device reading is compared to the simulator setting.

Parameter	Range	Mean Error	Standard Deviation
ECG Rates beats per minute	30 to 254	0	0
Tested 3 lead and 5 lead modes vs all leads at multiple amplitude settings spec ±2 bpm or ±2% (greater of)			
Oximetry % SpO_2	50 to 100%	0.25	0.45
Oximetry Pulse rate (bpm)	30 to 250	1.18	0.90
spec oximetery ±2% SpO_2 (min), rate ±2 bpm or ±2% (greater of)			
Repiration breaths per minute	4 to 150	0	0
spec breath rate ±1 bpm or ±5% (greater of)			

As the tables show the 3404 monitors very closely tracked the simulators. The maximum mean differences was 1.18 for SpO_2 pulse rate, all other values were less than one.

Clinical Tests:

Clinical studies were done on oximetry and respiration.

Oximetry:
A deep desaturation test was run on the 3404 oximeter at the VA Medical Center in Milwaukee under an approved IRB. The oximeter values were compared to an OSM-3 co-oximeter. Over the SpO2 range of 70% - 100% the standard deviation was 1.8 (spec = +/- 2). Over the SpO2 range of 50% - <70% the standard deviation was 2.4 (spec = +/- 3). R squared = 0.97 (measure of how true the regression line is, one being perfect).

Respiration:
The repiration values were collected from the 3404 and a BCI 9004 Capnograph (K970209) (a CO2 gas monitor). The test was conducted at BCI. Thirty volunteers were tested. Three readings were recorded from each subject; at rest, right after heavy exercise (bike) and after a cool down period. The minimum breath rate was 7 bpm and the maximum was 31 bpm. The mean difference between the 9004 and the 3404 readings was 0.63 with a standard deviation of 0.80. The accuracy specification of the 3404 respiration function is ±2 bpm or ±2%, whichever is greater. The 3404 agreed very closely with the 9004 respiration rate.

Performance Standards:

One performance standard was used. The ECG standard is ANSI/AAMI EC13-1992 standard (American National Standard for *Cardiac monitors, heart rate meters and alarms*).

ECG
The 3404 was tested to the requirements of AAMI EC13-1992. These requirements included reviews or tests for labeling, operating conditions, overload protection (includes defib tests), risk current (leakage), auxiliary output, respiration, leads-off sensing, active noise suppression, QRS detection, range & accuracy of heart rate meter, alarm system and ECG display capability requirements (including pacemaker). The 3404 met all of the applicable requirements.

The 3404 passed all the tests.

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 or better than 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

AUG 20 1998

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

Re: K981939
BCI Model 3404 Oximeter/ECG Monitor
Regulatory Class: II (two)
Product Code: DQA
Dated: May 29, 1998
Received: June 2, 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 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" (21CFR 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

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): K981939

Device Name: BCI 3404 Monitor

Indications For Use:

Intended Use

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The device will provide fast, reliable measurements on patients ranging from pediatric to adult when using the appropriate BCI accessories.

The monitor is not intended for home use. The monitor is not intended to be an apnea monitor. It was not designed or validated for use as an apnea monitor. The monitor is not intended for neonatal use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K981939

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