JUN 9 1999

K991086

Summary of Safety and Effectiveness

Submitter: Address:	BCI International, Inc. N7 W22025 Johnson Road Waukesha, WI 53186
Telephone:	(414) 542-3100
Contact:	VP Regulatory Affairs
Prepared:	March 26, 1999
Proprietary Name:	BCI Capnocheck® II
Common/Classification Name:	Capnograph with pulse oximeter and optional printer.
Predicate Devices:	BCI 8200 Capnometer (K941982) BCI 9000 Capnograph (K873856) BCI 9004 Capnograph (K970209)

New Device Description:

The BCI 8400 Capnocheck II monitor performs capnography and pulse oximetry using the same technology as existing legally marketed devices. Capnography data includes end-tidal CO_2 ($ETCO_2$), inspired CO_2 ($inCO_2$), and respiration rate measurements as well as a respiration breath indicator and $ETCO_2$ waveform. Oximetry data includes functional arterial blood oxygen saturation (%SpO_2) and heart rate measurements as well as pulse strength indicator and plethysmogram. This device is designed to provide full-featured monitoring capabilities in a lightweight, hand-held design. The system consists of a small hand held monitor with optional infrared linked printer and AC powered battery eliminator. Features include a gas inlet connection, an exhaust gas connection, an SpO_2 sensor interface, liquid crystal display (LCD), system status LEDs, function keypad, and infrared serial port. The LCD display has an electroluminescent (EL) backlight and displays patient data, waveforms, trends, breath and pulse rate indicators, alarm limit indicators, and messages. The keypad consists of six keys: power, waveform/trend, alarm silence, up and down arrows, and menu/enter. There are three system status LEDs: alarm silence, high and medium/low priority alarms. The infrared serial port is used for data communication with the optional printer.

Patient data can be printed up to every 15 seconds as it is collected or trends can be printed (text only).

Intended Use:

The 8400 Capnocheck II is a low cost CO_2 monitor with pulse oximeter and optional external printer. It may be used in the hospital or clinical environment, and during emergency land transport. It is not intended for use in the home. It is intended to be used in all critical environments, including ventilatory applications, patient ground transport, EMS (Emergency Medical Services) and anesthesia. The capnography parameter provides end tidal CO_2 ($ETCO_2$), inspired CO_2 ($inCO_2$), and respiration rate measurements on all patients from pediatric to adult. The oximetry parameter works with all BCI oximetry sensors, providing $\%SpO_2$ and pulse rate on all patients from pediatric to adult. The 8400 Capnocheck II permits continuous patient monitoring with adjustable alarm limits as well as visual and auditory alarm signals. It is not intended nor designed 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 to ensure that the BCI 8400 monitor was safe and would perform within the environment(s) for which it is to be marketed.

Safety testing was conducted in accordance with the *Reviewer's Guidance for Respiratory Devices, 1993*, EN60601-1, and several other international standards for medical devices. The monitor passes all of these tests and met all requirements of the standards.

Environmental testing was performed in accordance with the guidelines and standards found in the *Reviewer's Guidance for Respiratory Devices, 1993* and EN60601-1-2. Electromagnetic compatibility (EMC), electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing has been completed. The results demonstrated that the BCI 8400 monitor complied with the guidelines and standards and that it performed within its specifications and functional requirements.

Testing of device performance included clinical testing of the $ETCO_2$, respiration rate, and SpO_2 measurements made by the BCI 8400 monitor. Further performance testing of the capnography parameter was also conducted in accordance with EN 864 (international standard for capnography). In addition, a human factors review and long term alarm test were performed to demonstrate overall device performance. The results demonstrated that the BCI 8400 monitor performed within its specifications.

Comparison testing of the 8400 and the predicate BCI 9000 Capnograph/Oximeter was done to show that the performance of the $ETCO_2$, respiration rate, $\%SpO_2$, and heart rate parameters of the two devices are the same. Using simulators, measurements were made by both devices. The tests were run with simulator settings spanning the 8400's entire specification range. All measurements were within the specified tolerances of the monitors and

simulators. These data support substantial equivalence of the BCI 8400 monitor to the BCI 9000 monitor.

The testing described above indicate that there is no functional difference between the operation of the BCI 8400 Capnocheck II monitor and the predicate BCI 9000 Capnograph/Oximeter for $ETCO_2$, respiration rate, SpO_2, and heart rate measurements. Based on these results, 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: K991086
BCI 8400 Capnocheck® II Capnograph with Pulse Oximeter and Optional External Printer
Regulatory Class: II (two)
Product Code: 73 CCK
Dated: March 29, 1999
Received: March 31, 1999

Dear Mr. Alexander:

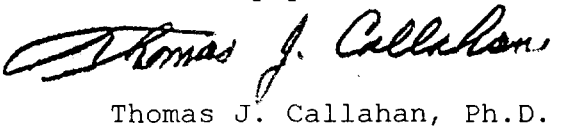
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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):_____

Device Name: BCI Capnocheck® II Monitor. Model 8400, Capnograph with Pulse Oximeter and optional external printer.

Indications For Use:

Intended Use:

The 8400 Capnocheck II is a low cost CO_2 monitor with pulse oximeter and optional external printer. It may be used in the hospital or clinical environment, and during emergency land transport. It is not intended for use in the home. It is intended to be used in all critical environments, including ventilatory applications, patient ground transport, EMS (Emergency Medical Services) and anesthesia. The capnography parameter provides end tidal CO_2 ($ETCO_2$), inspired CO_2 ($inCO_2$), and respiration rate measurements on all patients from pediatric to adult. The oximetry parameter works with all BCI oximetry sensors, providing $\%SpO_2$ and pulse rate on all patients from pediatric to adult. The 8400 Capnocheck II permits continuous patient monitoring with adjustable alarm limits as well as visual and auditory alarm signals. It is not intended nor designed 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 K991086

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