K031742

AUG 18 2003

Summary of Safety and Effectiveness

Submitter: Address:	BCI, Inc. N7 W22025 Johnson Road Waukesha, WI 53186
Telephone:	(262) 542-3100
Contact:	VP Regulatory Affairs
Prepared:	May 16, 2003
Proprietary Name:	BCI® MiniTorr Plus® NIBP monitor (model 6004) with new Nellcor pulse oximetry option.
Common/Classification Name:	Non-invasive blood pressure monitor/pulse oximeter
Predicate Devices:	BCI® 6004 NIBP monitor (K984618, K983796, K970801) Nellcor® Oximax N-550 Pulse Oximeter (K021090) Nellcor® N-595 Pulse Oximeter (K012891)

New Device Description:

The currently marketed BCI Mini-Torr Plus noninvasive blood pressure (NIBP) monitor with optional pulse oximeter, electronic thermometer and printer has been updated to include an additional Nellcor pulse oximeter option which uses the same technology as existing legally marketed devices. The BCI 6004 NIBP monitor with Nellcor pulse oximetry uses the Nellcor MP506 pulse oximetry module. This same module is used in the Nellcor Oximax N-550 Pulse Oximeter (K021090). The Nellcor MP506 board uses the same technology in a very similar design to that found in the Nellcor N-595 Pulse Oximeter.

This device is designed to provide full featured monitoring capabilities in a light weight, transportable design. The system consists of a small table top NIBP monitor with a desk top charger. Features include an NIBP cuff hose connection, an optional SpO_2 sensor interface, an optional temperature probe interface and holder, an optional internal printer, display of patient data via an LED display (systolic, diastolic, and mean arterial pressure, interval timer, SpO_2, pulse rate, pulse strength, temperature), system status LEDs (battery, sensor, alarm silence, alarm, and alert), and the function keypad area consisting of eleven keys (power,

start, cancel, stat, up and down arrows, interval, recall, manual/auto, alarm set, and alarm silence). The monitor has a serial port that is used for data communication.

Intended Use:

The 6004 NIBP monitor is a low cost portable NIBP monitor for spot checking or monitoring of a patient's systolic, diastolic and mean arterial (MAP) blood pressures, and pulse rate, with optional SpO_2, optional oral/rectal temperature, and/or integral printer. The device will provide NIBP measurements on patients ranging from neonate to adults when using the appropriate BCI blood pressure cuff. The monitor has two modes for NIBP monitoring: neonate and adult. An LED indicator illuminates when the monitor is configured for NIBP neonate mode. The BCI oximetry options work with all BCI oximetry sensors when providing SpO_2 and pulse rate on all patients from neonate to adult in both NIBP adult and neonate mode. The Nellcor oximetry option provides SpO_2 and pulse rate data on adult patients using the Nellcor DS 100A sensor. The electronic thermometry option is intended for intermittent "spot checks" of oral or rectal temperature for patients neonate through adult and requires WelchAllyn thermometry probes and probe covers. The temperature option works for all patients in NIBP adult or neonate mode. The device is intended for use in both clinical and ground EMS environments by health care professionals. It is not intended for home use.

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 6004 monitor would perform within the environment(s) for which it is to be marketed. Testing was performed in accordance with the guidelines and standards found in the reviewer's guides for respiratory devices. Electromagnetic compatibility testing to IEC 60601-1-2: 2001 has been completed and demonstrated that the BCI 6004 monitor was in compliance.

Comparison testing of the new 6004 with Nellcor pulse oximetry option and the predicate 6004 was done to show that the performance of the NIBP and electronic thermometry parameters of the two devices are the same (systolic, diastolic, and mean arterial pressures, NIBP heart rate, oral and rectal temperature). Comparison testing of the new 6004 with Nellcor pulse oximetry option and the Nellcor® N-595 Pulse Oximeter (K012891) was done to show that the performance of the SpO_2 measurements made by the two devices is the same.

Bench-top performance testing of the BCI 6004 NIBP monitor were performed by Nellcor using their proprietary simulators. They show that their MP506 pulse oximetry board when contained in the BCI 6004 monitor performs to its specifications.

A full software validation test of the BCI 6004 NIBP monitor with new Nellcor pulse oximetry option was completed. These tests showed that the device modifications operate as

intended and that the changes made do not compromise the overall performance of the monitor.

The testing described above indicate that there is no functional difference between the operation of the new 6004 NIBP monitor with Nellcor pulse oximetry option and the original 6004 NIBP monitor or Nellcor N-595 Pulse Oximeter. On the basis of 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

AUG 1 8 2003

Mr. Donald Alexander
Vice President of Regulatory Affairs
BCI, Incorporated
N7 W22025 Johnson Road
Waukesha, Wisconsin 53186-1856

Re: K031742
Trade/Device Name: BCI 6004 NIBP Monitor with Nellcor Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II (Two)
Product Code: DQA, DXN
Dated: May 23, 2003
Received: June 4, 2003

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 such 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 and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim 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 (if known): K031742

Device Name: BCI 6004 NIBP Monitor with Nellcor Pulse Oximeter.

Indications For Use:

Intended Use

The 6004 NIBP monitor is a low cost portable NIBP monitor for spot checking or monitoring of a patient's systolic, diastolic and mean arterial (MAP) blood pressures, and pulse rate, with optional SpO_2, optional oral/rectal temperature, and/or integral printer. The device will provide NIBP measurements on patients ranging from neonate to adults when using the appropriate BCI blood pressure cuff. The monitor has two modes for NIBP monitoring: neonate and adult. An LED indicator illuminates when the monitor is configured for NIBP neonate mode. The BCI oximetry options work with all BCI oximetry sensors when providing SpO_2 and pulse rate on all patients from neonate to adult in both NIBP adult and neonate mode. The Nellcor oximetry option provides SpO_2 and pulse rate data on adult patients using the Nellcor DS 100A sensor. The electronic thermometry option is intended for intermittent "spot checks" of oral or rectal temperature for patients neonate through adult and requires WelchAllyn thermometry probes and probe covers. The temperature option works for all patients in NIBP adult or neonate mode. The device is intended for use in both clinical and ground EMS environments by health care professionals. It 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)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031742

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

000007