JAN 22 1999

K983796

BCI INTERNATIONAL

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:	October 2, 1998
Proprietary Name:	BCI Mini-Torr Plus (model 6004) with new electronic thermometer option
Common/Classification Name:	Noninvasive blood pressure measurement system
Predicate Devices:	BCI 6004 NIBP monitor Welch Allyn 678 SureTemp Thermometer

New Device Description:

The currently marketed BCI Mini-Torr Plus noninvasive blood pressure (NIBP) monitor with optional oximeter, and printer has been updated to include an additional electronic thermometer option which uses the same technology as existing legally marketed devices. This device is designed to provide full-featured monitoring capabilities in a lightweight, transportable design. The system consists of a small tabletop NIBP monitor with a desktop 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 BCI Mini-Torr Plus monitor is a portable noninvasive blood pressure (NIBP) monitor for spot checking or monitoring of a patient's systolic, diastolic, and mean arterial (MAP) blood pressures, and pulse rate. Optional oximeter, electronic thermometer and/or integral printer are available. The device will provide fast, reliable NIBP measurements on patients ranging from children (pediatric) to adults when using the appropriate BCI blood pressure cuff. The oximetry option works with all BCI oximetry probes, providing SpO_2 and pulse rate on all patients from neonate to adult. The electronic thermometry option requires Welch Allyn thermometry probes and probe covers. It provides oral or rectal temperature information for patients neonate through adult.

The device is intended for use in both clinical and ground EMS environments by health care professionals. It is not intended for home use. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals for the NIBP and oximetry functions.

Performance Data:

The design of this device utilizes currently available technology found in many legally marketed devices. Testing was done to ensure that 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 and electronic thermometers. EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing has been completed. The results demonstrated that the BCI 6004 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.

Comparison testing of the new 6004 with temperature option and the predicate 6004 was done to show that the performance of the NIBP and oximetry parameters of the two devices are the same (systolic, diastolic, and mean arterial pressures, NIBP heart rate, SpO_2, and oximetry heart rate). Using simulator s, measurements were made by both devices. The tests were run with simulator settings spanning the 6004's entire specification range. The difference between measurements made by both devices (predicate – new) was calculated. The average difference between readings were -0.14 mmHg for systolic pressure, 0.07 mmHg for diastolic pressure, 0.07 mmHg for MAP, 0 bpm for heart rate measured with the NIBP parameter, 0% for SpO2 and 0 bpm for heart rate measured with the oximetry parameter. All measurements were within the specified tolerances of the monitors and simulators. These data support substantial equivalence of the NIBP and oximetry parameters of the new 6004 monitor to the original 6004 monitor.

Comparison testing of the new 6004 with temperature option and the Welch Allyn 678 SureTemp Thermometer was done to show that the performance of the temperature measurements made by the two devices is the same. Both the BCI 6004 and Welch Allyn 678 monitors were used to simultaneously measure temperature in a water bath over their

entire specified temperature range (84 – 108 °F). The average difference (predicate – new) between measurements made with both monitor was -0.04 °F, which is within the specified tolerance (± 0.2 °F).

The testing described above indicate that there is no functional difference between the operation of the new 6004 NIBP monitor with temperature option and the original 6004 NIBP monitor or Welch Allyn 678 SureTemp Thermometer. 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

JAN 22 1999

Mr. Donald J. Alexander
VP Regulatory Affairs
BCI International, Inc.
N7 W22025 Johnson Road
Waukesha, WI 53186

Re: K983796
6004 NIBP Monitor with Temperature
Regulatory Class: II (Two)
Product Code: 74 DXN
Dated: October 26, 1998
Received: October 27, 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'(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

Indications For Use

510(k) Number (if Known): K983796

Device Name: BCI Mini-Torr Plus Monitor. Model 6004, NIBP monitor with optional oximeter, electronic thermometer, and printer

Indications For Use:

Intended Use

The BCI Mini-Torr Plus monitor is a portable noninvasive blood pressure (NIBP) monitor for spot checking or monitoring of a patient's systolic, diastolic, and mean arterial (MAP) blood pressures, and pulse rate. Optional oximeter, electronic thermometer and/or integral printer are available. The device will provide fast, reliable NIBP measurements on patients ranging from children (pediatric) to adults when using the appropriate BCI blood pressure cuff. The oximetry option works with all BCI oximetry probes, providing SpO_2 and pulse rate on all patients from neonate to adult. The electronic thermometry option requires Welch Allyn thermometry probes and probe covers and provides oral or rectal temperature information for patients neonate through adult.

The device is intended for use in both clinical and ground EMS environments by health care professionals. It is not intended for home use. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals for the NIBP and oximetry functions.

(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 K983796

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