



K4110801

Summary of Safety and Effectiveness

NOV 12 1997

Submitter: BCI International, Inc.
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Waukesha, WI 53188

Telephone: (414) 542-3100
Contact: VP Regulatory Affairs

Prepared: March 3, 1997

Proprietary Name: BCI 6004 NIBP Monitor
Common/Classification Name: Noninvasive blood pressure measurement system

Predicate Devices: BCI 6100 Vital Signs Monitor

New Device Description:

The BCI 6004 NIBP monitor with optional pulse oximetry (SpO₂) and printer 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 light weight, transportable design. The system consists of a small table top non-invasive blood pressure monitor with a desk top charger. The system features an NIBP cuff hose connection, an SpO₂ probe interface, the optional internal printer, display of patient data via an LED display (Systolic, Diastolic, & Mean arterial pressure, Interval timer, SpO₂, Pulse Rate, Pulse Strength), system status LEDs (Battery, Probe, Alarm Silence, Alarm, & Alert), and the function keypad area consisting of eleven keys (O/I (off/on), START, CANCEL, STAT, Up and Down Arrows, INTRVL, RECALL, MANUAL/AUTO, ALARM SET, & Alarm Silence). The monitor has a serial port that is used for data communication. The model 6004 has two parameters, NIBP and SpO₂ plus the integrated printer.

Intended Use:

The 6004 NIBP monitor is a 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 SpO₂ and/or integral printer. The device will provide fast, reliable 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 SpO₂ and pulse rate on all patients from neonate to 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.

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 and standards found in the reviewers guide for respiratory devices. 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.

SpO₂ & HR

Performance testing between the new 6004 with the LOX board oximeter option and the predicate 6100 was done to show that the performance of the two devices is the same (SpO₂ & HR).

The SpO₂ simulator was the Biotek Index (K933519). All the SpO₂ results were within one count (max) of the simulator and each other. The same was true of heart rate until 240 bpm was run. Both devices were within 0 to 3 counts of each other and the simulator. The result was still within the device specification of +/- 2% (@ 240 -> 4.8 counts).

A deep desaturation test was run on the LOX board oximeter using the Capnograph Plus (9004) as the host at the VA Medical Center in Milwaukee under an approved IRB. The LOX values were compared to an OSM-3 co-oximeter. Over the SpO₂ range of 70% - 100% the standard deviation was 2.0 (spec = +/- 2%). Over the SpO₂ range of 50% - <70% the standard deviation was 2.7 (spec = +/- 3%). R squared = 0.97 (measure of how true the regression line is, one being perfect).

A test was run in-house comparing the 6004 with the LOX board to the 9004 with a LOX board to show that the device will give the same reading even if the host is different. Another monitor, the BCI 9000 Capnograph with Oximeter was also run at the same time. (BCI 9000 K873856). Again the SpO₂ simulator was the Biotek Index (K933519). All the SpO₂ results were within one count (max) of the simulator and each other. The same was true of heart rate until 240 bpm was run. All of the devices were within 0 to 3 counts of each other and the simulator. The result was still within the device specification of +/- 2% (@ 240 -> 4.8 counts).

NIBP

Performance testing for the NIBP function was composed of two sections. The first part was testing to the ANSI/AAMI SP10-1992 standard (American National Standard for *Electronic or automated sphygmomanometers*) & ANSI/AAMI/ISO SP10A-1996 Amendment to ANSI/AAMI SP10-1992. This test was to determine the accuracy of the NIBP technology using the MicroNIBP module. The next test showed that the 6004 monitor with the same hardware design, electronics and software as the MicroNIBP performed the same. The MicroNIBP design was moved into the 6004 design because of space and cost constraints.

The SP-10 testing was conducted under an approved IRB at the VA Medical Center in Milwaukee and at BCI International. When the MicroNIBP measurements are compared to the average of the manual readings the mean difference is -1.8 mmHg on systolic pressures and -2.6 mmHg on diastolic pressures. This meets the SP-10 requirement for a maximum mean difference of +/- 5 mmHg. The standard deviation of the difference between the MicroNIBP values and the average manual values was 7.1 mmHg for systolic pressures and 7.6 mmHg for diastolic

pressures. This falls within the 8 mmHg limit imposed by the SP-10 standard. The next test showed that the MicroNIBP and the 6004 NIBP monitor will give the same NIBP readings. Using the Dynatech Nevada CuffLink NIBP Analyzer as the NIBP simulator a series of readings were taken over the specification range. The CuffLink repeatability specification is +/- 1% of the selected target value. The test was run for heart rates from 30 bpm to 200 bpm (over the spec) and a pressure range (SYS/DIA) of 60/30 to 250/200 mmHg. Three readings were taken at each setting for both devices. An average of the three readings was calculated for both devices. Then the difference between devices was calculated. The average difference of all the readings were 1.0 for SYS, 1.1 for DIA, 1.1 for MAP and 0 for HR. This shows that the MicroNIBP and the 6004 NIBP monitor operate the same.

The 6004 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,

A handwritten signature in black ink that reads "Donald Alexander". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Donald Alexander
VP Regulatory Affairs



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 12 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

NOV 12 1997

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

Re: K970801
BCI Model 6004 NIBP Monitor
Regulatory Class: II (Two)
Product Code: 74 DXN
Dated: September 22, 1997
Received: September 23, 1997

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 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.

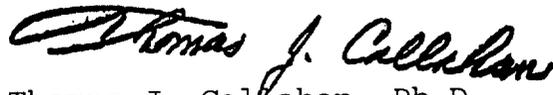
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Donald J. Alexander

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/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): K970801

Device Name: BCI 6004 NIBP Monitor

Indications For Use:

Intended Use

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K970801

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____