

SEP 25 1998



Summary of Safety and Effectiveness

Submitter: BCI International, Inc.
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 Waukesha, WI 53188

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

Prepared: May 29, 1998

Proprietary Name: BCI 9200 Vital Signs Monitor
 Common/Classification Name: Monitor, Electrocardiograph
 Predicate Devices: BCI 6200 Vital Signs Monitor
 BCI 9100 Multigas Monitor
 BCI 6004 NIBP Monitor
 Siemens SC6000 Bedside Monitor

New Device Description:

The BCI 9200 Vital Signs 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, two invasive pressure interfaces, two YSI compatible temperature interfaces, an NIBP cuff hose connection, an SpO₂ probe interface, the optional internal printer, display of patient and waveform data via a color LCD, system power status LEDs, a rotary control knob and the function keypad area consisting of five keys (on/off, zero (IP zero), NIBP start/stop, print start/stop & alarm silence). The monitor has a serial port that is used for data communications.

Intended Use:

The 9200 vital signs monitor is intended to be used in the ICU, CCU, OR, ER, RR, Labor and Delivery rooms, special procedure labs and other areas of the hospital or clinic where low end monitoring systems are needed. The basic monitor package includes ECG (3 lead / 5 lead), impedance respiration (RSP), non-invasive blood pressure (NIBP), pulse oximetry (SpO₂), two invasive blood pressures (P1 and P2), and two temperature channels (T1 and T2). A 2-inch internal, graphical/alphanumeric printer and a battery are provided as options. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The device will provide fast, reliable measurements on patients ranging from children (pediatric) to adults 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 9200 Vital Signs Monitor and its components were separated 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, NIBP and oximetry. Two performance standards were used for ECG (ANSI/AAMI EC13) and NIBP (ANSI/AAMI SP10).

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. The parameters tested were: ECG rate, Oximetry % SpO₂ & rate, NIBP rate, respiration rate, temperature, and IBP static pressure, systolic, diastolic & mean pressures plus pulse rate. The 9200 Vital Signs Monitors very closely tracked the simulators. All of the mean differences were less than one.

Clinical Tests:

Clinical studies were done on oximetry, respiration and NIBP.

Oximetry:

A deep desaturation test was run on the Newox1P OEM oximeter board (used in the 9200) 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 1.74 (spec = +/- 2). Over the SpO₂ range of 50% - <70% the standard deviation was 2.77 (spec = +/- 3). R squared = 0.91 (measure of how true the regression line is, one being perfect).

Respiration:

The respiration values were collected from the 9200 and a BCI 9004 Capnograph (K970209) (a CO₂ gas monitor). The test was conducted at BCI. Thirty one volunteers were tested. The minimum breath rate was 5 bpm and the maximum was 33 bpm. The mean difference between the 9004 and the 9200 readings was 0.57 with a standard deviation of 0.65. The accuracy specification of the 9200 respiration function is ± 1 bpm or $\pm 5\%$, whichever is greater. The 9200 agreed very closely with the 9004 respiration rate.

NIBP

The NIBP function of the 9200 is provided by the MicroNIBP module. The actual clinical data for the MicroNIBP module is contained in the SP10 report. The summary is contained in the following performance standards section. A mini-study was conducted at BCI with a 9200 containing the MicroNIBP module. Thirty one volunteers were tested and compared to a single human observer taking a manual NIBP reading at the same time (on the same arm). The accuracy requirement of the SP10 standard is a mean difference of ± 5 mmHg with a standard deviation of 8 mmHg. For the systolic readings the mean difference was 2.81 mmHg with a standard deviation of 2.34 mmHg. For the diastolic readings the mean difference was 3.45 mmHg with a standard deviation of 2.54 mmHg. The results are well within the SP10 requirements.

Performance Standards:

Two performance standards were used. The NIBP standard is ANSI/AAMI SP10-1992 standard (American National Standard for *Electronic or automated sphygmomanometers*) & ANSI/AAMI/ISO SP10A-1996 Amendment to ANSI/AAMI SP10-1992. The ECG standard is ANSI/AAMI EC13-1992 standard (American National Standard for *Cardiac monitors, heart rate meters and alarms*).

NIBP

Performance testing for the NIBP was composed of two sections. The first part was testing to the ANSI/AAMI SP10-1992 standard. This test was to determine the accuracy of the NIBP technology using the MicroNIBP module. The next test showed that the MicroNIBP module and the BCI 6004 NIBP monitor (K970801) performed the same. This is to support the accuracy of the MAP readings.

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 largest difference (of averages) for any setting was 4.3 mmHg. 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 module (used in the 9200) and the 6004 NIBP monitor operate the same.

ECG

The 9200 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 9200 met all of the applicable requirements.

The 9200 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



SEP 25 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K982279
ADVISOR Model #9200
Regulatory Class: II
Product Code: MHX
Dated: June 26, 1998
Received: June 30, 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,

A handwritten signature in cursive script that reads "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

Indications For Use

510(k) Number (if known): K982279

Device Name: BCI 9200 Vital Signs 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 K982279

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____