

K974697

Summary of Safety and Effectiveness

Submitter:	BCI International, Inc.	MAR 11 1998
Address:	W238 N1650 Rockwood Drive Waukesha, WI 53188	
Telephone:	(414) 542-3100	
Contact:	VP Regulatory Affairs	
Prepared:	December 15, 1997	
Proprietary Name:	3444 Reusable Finger Sensor	
Common/Classification Name:	Pulse Oximeter (accessory)	
Predicate Devices:	BCI 3044 Reusable Finger Sensor	

New Device Description:

The BCI 3444 Reusable Oximetry Finger Sensor is an updated version of an existing finger sensor, the 3044, legally marketed by BCI International. This updated finger sensor is designed to work with all BCI oximeters. The sensor is made up of three major parts, the cable with the molded connector, the top part of the shell containing the LEDs and the bottom part of the shell containing the photo detector.

Intended Use:

The 3444 Reusable Finger Sensor is used with BCI oximetry to noninvasively measure oxygen saturation (SpO₂), pulse rate and plethysmographic pulse waves. The 3444 sensor is recommended for patients weighing more than 15 kg and patients with limited activity.

The 3444 Reusable Finger Sensor is not recommended for prolonged use unless skin integrity is checked frequently and the measurement site is changed accordingly.

The Reusable Finger Sensor is for use with BCI International monitors and with monitors that contain BCI International oximetry or are licensed to use BCI International sensors.

Performance Data:

The design of this device utilizes currently available technology found in the predicate device and in many legally marketed devices. Testing was done to ensure that it would perform the same as the predicate device. This testing included sensor intensity (Red & IR light), drop test, 4 kV Hi-Pot test, surface temperature test and an operational test at extreme temperatures (0°F & 140°F). The 3444 sensor passed all the tests.

Clinically controlled desaturation studies were done to demonstrate that the 3444 with a BCI oximeter accurately displays the patient's blood oxygen level within the systems specified accuracy limits as compared to a co-oximeter (OSM-3). Statistical analysis on the data collected from the studies were compared to those from a co-oximeter during the controlled subject desaturation runs. The results from the clinical studies support the accuracy claims of the system (3444 with the oximeter), with a standard deviation of 1.73 for the measurement range of 70-100% (spec is 2) and 2.50 for the range of 50-69% (spec is 3).

Additional tests were run comparing the new 3444 sensor directly with the predicate 3044 sensor. These tests compared 89 sets of measurements on subjects where the two sensors (with oximeters) were used at the same time to take a reading. The maximum difference between readings was a count of one. The 3444 passed this set of tests.

On the basis of 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.

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 1998

Mr. Donald J. Alexander
BCI International
W238 N1650 Rockwood Drive
Waukesha, WI 53188-1199

Re: K974697
BCI 3444 Pulse Oximeter Sensor
Regulatory Class: II (two)
Product Code: 74-DQH
Dated: December 15, 1997
Received: December 16, 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.

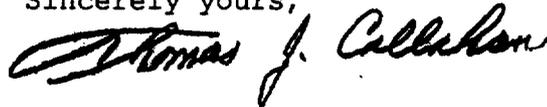
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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): K974697

Device Name: BCI 3444 Reusable Finger Sensor, (A Pulse Oximeter Accessory)

Indications For Use:

Intended Use

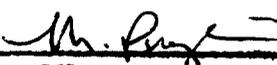
The 3444 Reusable Finger Sensor is used with BCI oximetry to noninvasively measure oxygen saturation (SpO_2), pulse rate and plethysmographic pulse waves. The 3444 sensor is recommended for patients weighing more than 15 kg and patients with limited activity.

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(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 K974697

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____