K991831

JUN 11 1999

10.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

Donald Brooks
Director of Operations
Boston Medical Technologies, Inc.
591 North Avenue, Suite 5
Wakefield, MA
Tel: 781.213.9200, Fax: 781.213.9233

This summary was prepared on June 10, 1999.

2. The name of this device is the ANScore™ System. The common name is ECG monitor and Respiration Pacer. Classification names are as follows:

Regulation Number	Classification Name
870.2340 74 DPS,IT	Electrocardiograph

3. The ANScore™ System is substantially equivalent to the following predicate devices: The qmed monitor one nDx (K972991), and the D.E. Hokanson, Inc. ANS2000 (K973426).

4. The ANScore™ System is a cart-based system with a computer-based user interface and data acquisition system for testing, data collection and data transmission for remote processing. The device features a 3 lead ECG, an optional blood pressure monitor, and a breathing apparatus.

5. The ANScore™ System has the same intended use as the legally marketed predicate Devices. The ANScore™ System is intended for use in heart rate variability measurements in response to paced respiration and controlled exercises. It is not intended for any specific clinical diagnosis. Assessment is indicated for patients in the physician office or hospital environment.

6. The ANScore™ System operates using the same monitoring technology employed in the predicates. The measurement technology and the transmission of ECG signals are similar and therefore the technological characteristics are essentially the same as those of the legally marketed predicate devices.

7. The ANScore™ System was subjected to safety and performance tests against applicable recognized standards. Final testing for the system included various performance tests to confirm compliance with functional requirements and performance specifications. Psysiological input was simulated using calibrated instrumentation representative of a range of test subjects and physiological states. A usability study of the ANScore™ System was performed by clinicians to validate ease of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1999

Mr. Donald James Sherratt
Boston Medical Technologies, Inc.
Intertek Testing Services
70 Codman Hill Road
Boxborough, MA 01719

Re: K991831
ANScore™ Health Management System
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: May 26, 1999
Received: May 28, 1999

Dear Mr. Sherratt:

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

Enclosure

Indications for Use Statement

510(k) Number K991831

Device Name The ANScore™ System

Indications for Use Indications: The ANScore™ System is intended for use in heart rate variability measurements in response to paced respiration and controlled exercises. It is not intended for any specific clinical diagnosis. Assessment is indicated for patients in the physician office or hospital environment

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

Prescription Use ✓
(Per 21 CFR 801.109)

510(k) Number Over-The-Counter Use