

AUG 11 2000

K 993875

**510(k) Summary for Boston Medical Technologies, Inc. (BMT)
Anscore™ Health Management System (“Anscore™”)**

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

Submitter:

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Tel: 781.213.9200, Fax: 781.213.9233

This summary was prepared on July 26, 2000.

Name of Device: The name of this device is the Anscore™ Health Management System. The common name is ECG monitor and Respiration Pacer. Classification names are as follows:

Regulation Number	Classification Name
870.2340 - 74 DPS, II	Electrocardiograph

Predicate Device: The Anscore™ Health Management System is substantially equivalent to the previously 510(k)-cleared Anscore™ Health Management System (K991831).

Intended Use: The Anscore™ has the same intended use as the legally marketed predicate devices. The Anscore™ system is intended for use in heart rate variability (HRV) measurements in response to paced respiration and controlled exercises.

Description Device: The Anscore™ 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 and a breathing apparatus, in order to conduct heart rate variability testing. Heart rate variability testing is one of various measurement tools used by physicians in their assessment of autonomic function and dysfunction.¹

Technical Characteristics: 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.

¹ See The American Association of Clinical Endocrinologists Medical Guidelines for the Management of Diabetes Mellitus: The AACE System of Intensive Diabetes Self-management - 2000 Update, *Endocrine Practice* 2000; 6(1):43-84; American Heart Association, 1999. AHA Scientific Statement: Diabetes and cardiovascular disease. *Circulation* 100:1134-1146; Assessment: Clinical autonomic testing report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*, 1996;46:873-880; Consensus Statement: Report and recommendations of the San Antonio Conference on Diabetic Neuropathy. *Diabetes* 1988;37:1000-1004; Proceedings of a consensus development conference on standardized measures in diabetic neuropathy. *Autonomic nervous system testing. Neurology* 1992; 42(9):1831-1837; Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology. Heart rate variability: standards of measurement, physiological interpretation, and clinical use. *Circulation* 1996; 93(5):1043-1065; R. Freeman. Noninvasive evaluation of heart rate variability: the time domain. In Low, PA (ed.) *Clinical Autonomic Disorders*, 2nd ed. Lippincott-Raven Publishers, 1997:297-307; Anonymous. The effect of intensive diabetes therapy on measures of autonomic nervous system function in the Diabetes Control and Complications Trial (DCCT). *Diabetologia* 1998; 41(4):416-423; A.I. Vinik and S. Suwanwalaikorn. Autonomic Neuropathy. In deFronzo, R.M. (ed.) *Current Therapy of Diabetes Mellitus*. Yearbook Inc. 1997;165-176; D.J. Ewing. Cardiac Autonomic Neuropathy. In Jarret (ed.) *Diabetes and Heart Disease*. Elsevier, 1984;99-132; D. Ziegler et al. Effects of treatment with antioxidant alpha-lipoic acid on cardiac autonomic neuropathy in NIDDM patients: a 4-month randomized controlled multi-center trial (DEKAN Study). *Diabetes Care* 1997;369-373; H. Genovely and M.A. Pfeifer, 1988. RR-variation: the autonomic test of choice in diabetes. *Diabetes/Metabolism Review* 4(3):225-271.

Performance Data: The Anscore™ system is the same as the previously 510(k)-cleared Anscore™ Health Management System and, thus, the results of the performance testing for that cleared system apply to this device. Final testing for the system included various performance tests to confirm compliance with functional requirements and performance specifications. Physiological input was simulated using calibrated instrumentation representative of a range of test subjects and physiological states.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 11 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Cesidio Tempesta
Boston Medical Technologies, Inc.
591 North Avenue, Suite 5
Wakefield, MA 01880-1641

Re: K993875
BTM Anscore™ Health Management System
Regulatory Class: II (two)
Product Code: DPS
Dated: July 14, 2000
Received: July 14, 2000

Dear Mr. Tempesta:

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.

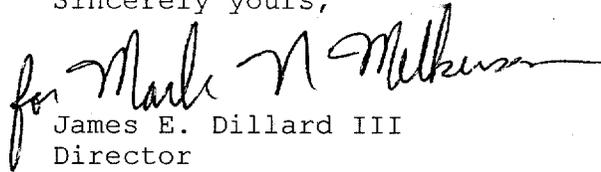
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,

for Mark N. Milburn

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K993875

Device Name The ANScore™ Health Management System

Indications for Use The ANscore™ system is intended for use in heart rate variability (HRV) measurements in response to paced respiration and controlled exercises.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Mark N. Milburn
Division of Cardiovascular & Respiratory Devices
510(k) Number K993875