K983550

JAN 7 1999

510(K) SUMMARY

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.

The assigned 510(k) number is:K#983550.

1. Submitter's Identification:

Bio-Monitoring International Corporation
P.O. Box 52614
Shreveport, LA 71135
Contact Person: Mr. Samuel J. Caldwell, President

Date Summary Prepared: October 28, 1998

2. Name of the Device:

XYZ System

3. Predicate Device Information:

J&J Physicdata I-330 System, K#945826

4. Device Description:

The XYZ System contains 5 major parts: The Amplifier Modules, The Amplifier Housing with Isolatrion Amplifiers and Isolated Power, the Analog to Digital Converter, the IBM-PC compatible computer and XYZ Software.

5. Intended Use:

The XYZ System is intended for biofeedback for relaxation and re-education of muscles.

6 Comparison to Predicate Devices:

Comparison Points	Physiodata I-330 System 510(k) #K945826	XYZ System System	Difference
Indication Statement	Biofeedback, Relaxation Training, and Physiological Monitoring	Biofeedback, Relaxation Training, and Physiological Monitoring	None
Intended Use	1)Provide electrical isolation between patient connected sensors and AC line powered equipment used to record and display signals from the sensors 2)Provide displays in software of the signals with visual and auditory displays 3)Collect and record the data from the signals	1)Provide electrical isolation between patient connected sensors and AC line powered equipment used to record and display signals from the sensors 2)Provide displays in software of the signals with visual and auditory displays 3)Collect and record the data from the signals	None
Effectiveness	Effective	Effective	None
Hardware Instrumentation Amplifiers	J&J I-330 Amplifier Modules	J&J I-330 Amplifier Modules and CapScan Amplifier	Uses same J&J I-330 amplifier modules, as well as, CapScan EEG/EMG amplifier
Software Program	Use System (Their Trade Name)	XYZ System Software	Similar
Software Features	Auditory and Visual Representations of the signals, data recording	Auditory and Visual Representations of the signals, data recording	None
Performance Standards	Requirements Met	Requirements Met	Minimal
Electrical Safety	Safe	Safe	None

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Performance standards met include UL-544 (electrical isolation), software validation requirements and testing procedures for the multi-channel isolation board.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

The XYZ System is substantially equivalent in intended use, design, material and technology as the J&J Physiodata I-330 System, K#945826. Both devices have the same intended use, similar software program, minimal differences in performance parameters and meet electrical safety requirements. Regarding software, the XYZ System uses the same Physiodata I-330 amplifier modules as well as the CapScan EEG/EMG amplifier. The XYZ System does not incorporate any changes in intended use, method of operation, material or design that could affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 1999

Anand Akerkar, Ph.D.
Official Correspondent
Bio-Monitoring International Corporation
Post Office Box 52614
Shreveport, Lousiana 71135

Re: K983550
Trade Name: XYZ System
Regulatory Class: II
Product Code: HCC
Dated: October 2, 1998
Received: October 9, 1998

Dear Dr. Akerkar:

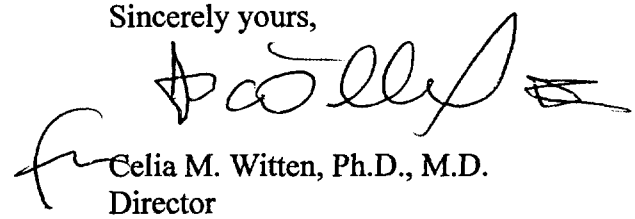
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT #3

510(k) NUMBER (IF KNOWN): K# 983550

DEVICE NAME: Bio-Monitoring International Corporation XYZ System

INDICATIONS FOR USE:

The XYZ System is intended for biofeedback for relaxation and re-education of muscles.

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Neil R P Ogden

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 983550