K 130158

510(k) Summary

BioResearch Associates, Inc.
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Official Correspondent: John Radke
24 July 2013

JUL 25 2013

Trade Name: M-Scan

Common Name: 2-channel, portable, battery operated electromyography

Regulation Number: 21 CFR 890.1375

Regulation Name: Diagnostic Electromyography

Regulatory Class: Class II

Product Code: KZM

Equivalent Device: BioEMG III (K082927)

Previous submissions: None

Product Description:

The M-Scan is a 2-channel, portable, battery operated electromyographic amplifier which includes: a) two (2) identical high-gain differential input amplifiers, b) two (2) buffer amplifiers, c) two (2) full wave rectifiers, and d) two (2) integrators. The overall amplification of the M-Scan is calibrated to 2500. The bandwidth filtering is set (fixed) from 30 Hz to 1000 Hz (± 3dB). The common mode rejection ratio is ≥ 130 dB at the power line frequency (50/60 Hz). The M-Scan does not include isolated power converter since it is battery operated, portable, and does not interface with any external equipment (it is never connected to the a-c line). Only three (3) functions are provided by the M-Scan: 1) amplification, 2) bandwidth limiting, and 3) integration of the signal for the integrated display.

Intended Use of electromyography: (same as for the BioEMG III – K082927)

1. To record electrical activity of 2 muscles of the stomatognathic system, especially temporalis or masseter
2. To clinically monitor 2 different muscles as an aid in the diagnosis and treatment evaluation by recording the electrical activity of muscles of the stomatognathic system
3. To determine the degree of relaxation (intra-patient) of 2 muscles at rest
4. To measure relative (intra-patient) levels of activity of 2 muscles during a functional act

Technological Characteristics:

The technological advantages of the M-Scan (compared to the predicate device) include:

1. The M-Scan is a portable, self contained, battery operated unit with no requirement for any external connections.
2. The M-Scan is dedicated to simple tests comparing two muscles at rest or in function.
3. Due to its simplicity and low-power electronic components, the M-Scan will use less energy than the predicate device.
4. The functional characteristics of the M-Scan amplifiers are essentially identical to those of the BioEMG III (K082927); literally the same I.C. components are used. See Appendix G.
5. New features of the M-Scan include: a) miniaturized, self contained operation, b) built-in rectification and averaging filter hardware, and c) built-in digital display

Non-Clinical Test Data:

Utilizing a calibrated function generator and oscilloscope we have applied test signals to both instruments. In Appendix E we have supplied comparable graphic plots of the waveforms and the frequency response characteristics of both instruments. In the M-Scan it is clear that we have retained comparable levels of amplification and band-pass filtering as used in the BioEMG III predicate device. EMG testing was performed on the M-Scan. Software validation testing was performed on the software for the M-Scan. This submission does not contain clinical data.

Conclusion:

Based on the information provided concerning the M-Scan device, M-Scan is substantially equivalent to the declared predicate of the BioEMG III (K082927).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 25, 2013

BioResearch Associates, Incorporated
C/O Mr. John Radke
President
9275 North 49th Street, Suite 150
BROWN DEER WI 53223

Re: K130158
Trade/Device Name: M-Scan
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic Electromyography
Regulatory Class: II
Product Code: KZM
Dated: June 25, 2013
Received: June 28, 2013

Dear Mr. Radke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130158

Device Name: **M-Scan**

Indications for Use:

Indications for use: 2 channel, hand held, mobile EMG amplifier

1. To record electrical activity of 2 muscles of the stomatognathic system, especially temporalis or masseter
2. To clinically monitor 2 different muscles as an aid in the diagnosis and treatment evaluation by recording the electrical activity of muscles of the stomatognathic system
3. To determine the degree of relaxation (intra-patient) of 2 muscles at rest
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(PLEASE TO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes
(Pat 21 CFR 801 subpart D)

AND/OR

Over-the-counter Use _____
(Part 21 CFR 801 subpart D)

Andrew I. Steen -S
2013.07.25 11:27:10 -04'00' FDA

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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