Special 510(k)
Myotronics-Noromed, Inc

510(k) SUMMARY

SEP 2 9 2011

Model MES 9200/EMG System

510(k) # K111687

Myotronics-Noromed, Inc.
5870 S. 194th St.
Kent, WA 98032
Telephone (206) 243-4214
Contact: Fray Adib, President

June 13, 2011

Device: Model MES 9200 EMG System for surface electromyography (SEMG).

Legally marketed predicate device: Model MES 9000 EMG System, K-013399

Description of the Device: The device incorporates circuitry enabling the same capabilities as the predecessor device. It is a computer based system offering options capable of evaluating muscle groups at rest or in function by means of surface electromyography. Muscle activity is quantified by means of re-usable or disposable surface electrodes positioned over the muscle groups being studied. Up to eight sites can be monitored simultaneously and displayed in time or frequency domains. The device is essentially identical to the predecessor device except that it utilizes wireless (Bluetooth) technology to transfer EMG data to host computer without a cable and to eliminate any connection between the patient and line voltage.

Intended Use: Used in evaluation and recording of muscle status, at rest and in function, as an aid in muscle re-education and muscle relaxation therapy, and to provide ability to compare new captured data with past data to assess progress in treating patients relaxation state.

Comparison with predicate devices: The Model MES 9200/EMG System has the same intended uses and fundamental scientific technology as its predecessor, the Model MES 9000. The design change which is the subject of this premarket notification is to transfer EMG data to host computer without a cable and to further increase the device's safety through use of a battery operated EMG unit and Bluetooth wireless technology to eliminate any possible connection between the patient and line voltage.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Myotronics-Noromed, Inc.
% Mr. Fray Adib
President
5870 S. 194th Street
Kent, WA 98032-2126

SEP 29 2011

Re: K111687
Trade/Device Name: Model MES 9200 EMG System
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback device
Regulatory Class: Class II
Product Code: HCC
Dated: August 22, 2011
Received: August 30, 2011

Dear Mr. Adib:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Kevia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K111687

Device Name: Model MES 9200/EMG System

INDICATIONS FOR USE

- For evaluation of the status of muscles at rest and in function
- As an aid in muscle re-education and muscle relaxation therapy
- Provides ability to compare new captured data with past data to assess progress in treating patients relaxation state

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

510(k) Number: K111687

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111687