MYOTRONICS-NOROMED, INC.
Leading in Musculoskeletal Evaluation Technologies For 30 Years

Special 510(k)
Myotronics-Noromed, Inc

510(k) SUMMARY

NOV 1 3 2001

Model MES-9000/EMG System

510(k) # K013399

Myotronics-Noromed, Inc.
15425 – 53rd Avenue South
Tukwila, WA 98188
Telephone (206) 243-4214
Contact: Mr. Fray Adib, President

October 9,2001

Device: Model MES-9000/EMG System consisting of computer-based surface electromyography (SEMG).

Legally marketed predicate devices: Model ND-2000 (K922838A), ND-8000 (K922270 & K992439) Myotronics-Noromed, Inc.

Description of the Device: The device incorporates circuitry enabling the capabilities of the two predecessor devices to be offered as a single 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.

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-9000/EMG System will have the same intended uses and fundamental scientific technology as its predecessors, the Models ND-2000 and ND-8000. The design change which is the subject of this premarket notification is to update and enhance the electronic components and software to state-of-the-art and to provide the capabilities of the two predecessor devices as a single device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2001

Mr. Fray Adib
President
Myotronics-Noromed, Inc.
15425 53rd Avenue South
Tukwila, Washington 98188

Re: K013399
Trade/Device Name: Model MES-9000/EMG System
Regulation Number: 882.5050
Regulation Name: Biofeedback device
Regulatory Class: II
Product Code: HCC
Dated: October 9, 2001
Received: October 15, 2001

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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. Melkerson

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

Enclosure

NOV 1 3 2001

510(k) Number (if known): K013399

Device Name: Model MES-9000/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)

for Mark N Milhorn

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013399

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

510(k) Number: _____

Device Name: Model MES-9000/EMG System