

AUG 13 1999



MYOTRONICS-NOROMED, INC.

Leading in Musculoskeletal Evaluation Technologies For Over 25 Years

Attachment 4

510 (k) SUMMARY

K 992439

~~K 822270~~

1. Submitter's Information

Date of Submission: July 20, 1999

Name & Address:

Myotronics-Noromed, Inc
15425 - 53rd Ave., S, Tukwila, WA 98188
Tel: (206) 243-4214 Fax: (206) 243-3625

Contact Name: Mr. Fray Adib

2. Device Trade Name: Norodyn 8000 SEMG System
Common Name: Surface EMG System
Classification Name: Device, Biofeedback

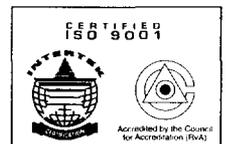
3. Myotronics-Noromed's intended addition of Fast Fourier Transformation (FFT) of data to the Norodyn 8000 software is substantially equivalent to that feature found in:

ProComp DSP & ProComp mfd. by Thought Technology, Inc.
Myosystem 1000 Electromyograph mfd. by Noraxon
I-330 Physiological Monitor mfd. by J & J Engineering

4. Description of the Device:

The Norodyn 8000 is a surface electromyographic device that measures and records the electrical potential emanating from muscle.

5. The feature being added to the software of this device, Fast Fourier Transformation (FFT) of captured data, has the same technological characteristics as other legally marketed devices described in the Special 510(k).





Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1999

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

Re: K992439
Trade Name: Norodyn 8000 SEMG System
Regulatory Class: II
Product Code: HCC
Dated: July 20, 1999
Received: July 22, 1999

Dear Mr. Adib:

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.

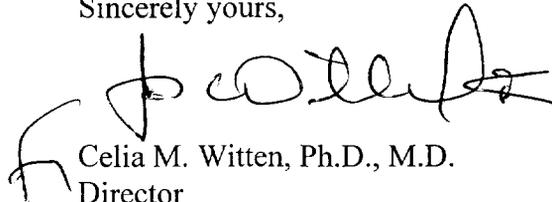
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 – Mr. Fray Adib

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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

510(k) Number (if known): K 99-2439

Device Name: Norodyn 8000 SEMG 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 patient's relaxation state

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

K992439

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____