



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2005

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

Re: K992694

Trade/Device Name: Model K6-I Diagnostic System
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic electromyograph
Regulatory Class: II
Product Code: KZM and NFS
Dated: August 11, 1999
Received: August 12, 1999

Dear Mr. Adib

This letter corrects our substantially equivalent letter of September 10, 1999, regarding the classification of your device which was incorrectly identified in the previous letter.

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 (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 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 continue 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), please contact the **Office** of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

510(k) Number (if known): K 992694

Device Name: Model K6-I Diagnostic System

Indications for use

For Jaw Tracking functions of this device:

- Tracks mandibular movement and position
- For the diagnosis of functional disorders such as **TMJ/MPD** syndrome, muscle tension, **bruxing**, and instability of occlusion
- **Identification** of mandibular **rest** position
- **Identification** of **interocclusal** distance and freeway space
- Monitors the position of the jaw in three dimensions
- Represents the spatial position of the mandibular incisal edge relative to the skull

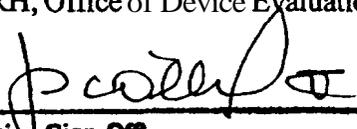
For electromyographic function of this device:

- Intended for use for muscles of mastication, especially **temporalis**, masseter, and digastric
- Designed to perform a limited number of functions in dental diagnosis

(continued on page 2)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K992694

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

510(k) Number: K 992694

Device Name: Model K6-I Diagnostic System

Indications for use = **electromyographic** functions of this device (continued from page 1)

- For use as a stand alone system for clinical monitoring of up to eight different muscles. it is ideally suited for diagnosis and treatment evaluation by recording **function/dysfunction** of the muscles of the stomatognathic system
- The determination of the degree of relaxation of a particular muscle or muscle group at rest
- The precise measurement of relative levels of contraction of several muscles during a functional test

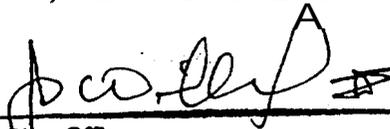
For both functions of this device:

- Diagnosis and management of **TMJ/MPD** disorders, orthodontic patients, denture patients, and reconstruction patients.

The addition of the feature described in this new **Premarket** Notification does not expand upon the above indicated uses.

(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

K 992694

Prescription Use *K*
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

SEP 10 1999



MYOTRONICS-NOROMED, INC.

Leading in Musculoskeletal Evaluation Technologies For Over 25 Years

Attachment 4

K 992694

510(k) SUMMARY

~~K-992158~~

1. Submitter's Information

Date of Submission: August 11, 1999

Name and address:

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

Contact Name: Mr. Fray Adib

2. Device Trade Name: Model K6-I Diagnostic System
Common name: Surface EMG System
Classification name: Electromyograph

3. Myotronics-Noromed's intended addition of Fast Fourier Transformation (FFT) of data to the K6-I Software is substantially equivalent to that feature found in:

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

4. Description of the device:

The Model K6-I Diagnostic System is a surface electromyographic device that measures and records electrical potential emanating from muscle (in addition to its ability to track and document mandibular position/range of motion).

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 above and in the Special 510(k).

