DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2005

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

Re: K970116
Trade/Device Name: ESG-1 Electrosonograrn (ESG-1)
Regulation Number: 21 CFR 872.2050
Regulation Name: Dental sonography device
Regulatory Class: I
Product Code: NFQ and NFS
Dated: January 10, 1997
Received: January 13, 1997

Dear Mr. Adib

This letter corrects our substantially equivalent letter of April 2, 1997, regarding the classification of your device which was incorrectly identified as "unclassified."

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.

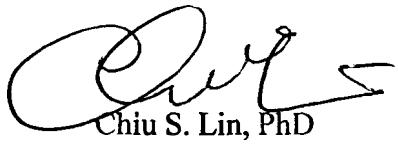
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Enclosure

510(k) Number (if known): _____

Device Name: ESG-1 Electrosonogram, Version 3.0-S

Indications For Use:

The original 510(k) for this device, K-905449/A, contained the following indications for use:

> "The ELECTROSONOGRAM ESG-I is a non-invasive device that measures and records sounds emitted from the temporomandibular (jaw) joint along with the relative position of the jaw as a means of assessing the status of the temporomandibular joint."

This 510(k) does not expand upon those indications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K970116

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

(Optional Format 1-2-96)

K970116

APR -2 1997

MYO-TRONICS, INC.

510(k) SUMMMARY

1. Submitter's Information

Date of Submission: January 10, 1997
Submitter's name and address:

Myo-tronics, 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: ESG-1 Electrosonogram or Sonograph
Common name: Temporomandibular Joint Sound Recorder
Classification name: Unclassified

3. Myo-tronics' ESG-1 Electrosonogram is substantially equivalent to: SONOPAK/QS manufactured by BioResearch of Milwaukee, Wisconsin.

4. Description of the device:

ESG-1 Electrosonogram is a non-invasive device that measures and records sounds emitted from the temporomandibular joint along with the relative position of the jaw as a means of assessing the status of the temporomandibular joint.

5. The ESG-1 Electrosonogram has the same technological characteristics as the above mentioned predicate device.