K943535

510(k) Summary

JUN 25 1997

General Information

Classification	Class II
Common Name	Biofeedback device, EMG Device
Trade Name	ME300 Muscle Tester
Manufacturer	Mega Electronics, Ltd. Savilahdentie 6 PO Box 1750 70211 Kuopio Finland tel: 358 71 282 8959
Submitted by	Regulatory Strategies, Inc. Consultant to Mega Electronics, Ltd.

Predicate Devices

Myotrac from Thought Technology	K881416
Myoexcerciser from Verimed	K832714

Device Description

The ME300 is a portable, battery powered EMG recorder.

Technological Characteristics

The ME300 is an electronic device used to gather and display electrophysiological signals obtained from muscle activity. These signals are used in programs related to muscle re-education and relaxation training.

The signals are received via conductive adhesive skin electrodes and may be displayed or stored for display at a later time. Signals may be gathered from two channels. Data downloading or transfer is via a standard fiber optic cable to a PC. The product does not relay any electrical or stimulatory signals to the body. It is only a signal recorder with display capabilities.

Intended Use

The intended use of the Model ME300 Muscle Tester is to record EMG sensory feedback signals to be used in various programs of muscle re-education and relaxation training.

Testing

The ME300 was tested for electrical and EMC safety by a recognized third party testing facility. The product meets the requirements of IEC 601-1-2, IEC 801-2, IEC 801-3, EN55011 and the EMC Directive.

Summary of Equivalence

The ME300 offers the user a means to gather electrophysiological signals (EMG) and display these signals for the purpose of muscle re-education and relaxation training. The indications for use and the basic overall design are either identical or substantially equivalent to the predicate products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gregory J. Mathison
Regulatory Strategies, Inc.
1660 Riverton Point
Eagan, Minnesota 55122

JUN 25 1997

Re: K943535
Trade Name: Model ME300 Muscle Tester
Regulatory Class: II
Product Code: 84HCC
Dated: March 28, 1997
Received: March 28, 1997

Dear Mr. Mathison:

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 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.

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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

510(k) Number (if known): K943535

Device Name: ME300 Muscle Tester

Indications For Use: ME300 is an electronic device used to gather and display electrophysiological signals obtained from muscle activity. These signals are used in programs related to muscle re-education and relaxation training.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K943535

Prescription Use X
(Per 21 CFR 801.109)

[redacted]