



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 1997

Mr. Joe Elrod
Manager of Regulatory Affairs
Chattanooga Group, Inc.
4717 Adams Road
P.O. Box 489
Hixson, Tennessee 37343-0489

Re: K972487
Trade Name: EMG Retrainer
Regulatory Class: II
Product Code: 84HCC
Dated: June 5, 1997
Received: July 2, 1997

Dear Mr. Elrod:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

Page 2 - Mr. Joe Elrod

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 at (301) 443-6597.

Sincerely yours,



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

Enclosure



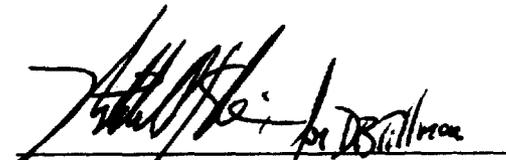
510(k) Number (if known): K972487

Device Name: Chattonooga Group, Inc.

- Indications For Use:**
1. To determine the activation timing of muscles.
 - a) retraining of muscle activation
 - b) coordination of muscle activation
 2. An indication of the force produced by muscle
 - a) control and maintenance of muscle contractions
 3. For use in relaxation training and muscle re-education.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K 972487

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

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K972487
Sept. 26, 1997

CHATTANOOGA
GROUP, INC.

510(K) SUMMARY

Date: June 5, 1997
Contact Person: Joe Elrod
Product: EMG Retrainer
Classification Name: Diagnostic Electromyograph
Classification: Class II

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Substantial Equivalence: The new device is a stand alone portable device for the measurement of muscle activity. It is similar to The Prometheus Group Pathway II Electromyography (510(k) K891732), Verimed Myoexerciser II (510(k) K892649), and Thought Technology Myotrac (510(k) K915858). [Reference Comparative Specifications on page 2-2].

System Description: The EMG Retrainer is a device used to measure the bioelectrical signals produced by muscle activity. The main display will register activity and display the quantitative measurement with an analog bar display. Targets of muscle activity may be stored (utilizing audible signals on demand) configurable for activity that is within established limits or exceeding those limits depending on user preference. The EMG Retrainer also contains an auto-ranging function which eliminates manual scale adjustments unless that is the preference. The auto-ranging feature as well as the targeting function are not available on the other models and will be quite useful to the healthcare professional.

Intended Use: The EMG Retrainer measures electrical activity of the muscle. Since the electrical activity of the muscle increases as the muscle tension increases and decreases as muscle tension decreases, EMG can provide information about the state of muscle tension.

Chattanooga Group, Inc.
4717 Adams Road
P.O. Box 489
Hixson, TN 37343-0489
Phone: 423-870-2281
Fax: 423-874-0287

COMPARATIVE SPECIFICATIONS

Feature	VERIMED	Myotrac	Prometheus Pathway	Chattanooga Single & Dual
Product Name	Myoezerciser II	4001	MR20	EMG
Pickup Config	individual electrodes	Triangular Pattern	DeLuca in-line or Proprietary	Triangular or individual electrodes
Active Head	No	Yes	Yes for Proprietary	No
Input Imped.	>10M ohm	1,000,000 M ohm	unknown	1,000,000 M Ohm with 4pF
Input Noise				<1uV RMS
Display Type	4 lines x 20 characters 5 lines x 25 characters	13 LED Dot Bar chart	16 char LCD histograms with log output 4 LED s	Custom LCD, dual 25 Seg Bar Chart plus overflows, 3 by 7seg digit signal level per channel, plus volume, & progr. Select digit
Operator Controls	12 Membrane Buttons	Volume & Gain Knobs Range Slide Switch Mode/On/Off switch	6 Membrane Buttons	5 Silicone Keypad Buttons; On/Off; Up, Down, Select & OK
Channels	2	1	2	1 or 2
Frequency Ranges	25 to 1000Hz	100 to 200Hz 20 to 500Hz	20 to 500 Hz "no notch filter"	15Hz to 300Hz (12db/Octave filter)
Buzzer	yes	Yes	Yes	3 Tone
Output Voltage	yes	Yes 0 to 2V	No (data by comma)	No
CMRR 50 Hz, 60 Hz	140dB	>180 dB	unknown	>100db
CMRR over frequency	120dB	>130 dB	>110 dB	>120db
Input Ranges (rms)	8 ranges	0.8 to 20uV 0.8 to 200uV 0.8 to 2000uV	1 to 800 uV true RMS	1uV to 2000uV Internal auto gain selection 8 Ranges
Electrode Wire	2 core + Screen	2 core + Screen	4 conductors	2 core + Screen
Earpiece	yes	Yes 2.5mm Phono 8 to 32 Ohm	Yes	Yes 2.5mm Phono
Threshold		Above & Below	Above & Below & Difference	Above, Below & At Target per channel
Threshold Features		N/A	Separate Hi/Lo indicating Leds	Bar Chart Dynamic Indication, set by manual, direct activity or % of activity.
Threshold Lock		4 seconds then switch to deactivate	unknown	Yes, Dynamic Threshold Setting.
Continuous Alarm	Yes, Varying pulse rates	Yes	unknown	Yes, Varying pulse rates
Stimulator	yes	No	Isolated Relay	No
Historical Record	yes	N/A	32 Training Sessions	9 training sessions
Battery Type	9V	9V	9V	3V Using AA cells
Battery Compartment	Slide open	Slide open	Slide open	Slide open
Power Consumption		6 to 11 mA Alkaline for 50 hrs	unknown Battery for 25Hrs	10 mA w/ Management power. Carbon, Alkaline or Ni Cad
Dimensions	85W*140L*30H	61W*112L*28H	117*69*38mm	81W*84L*40D
Weight	180g	70 g +bat.	280g	150g
Pocket Clip	Yes	Yes	Yes	Yes



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