NOV 17 1998

K983048

510(k) SUMMARY

A. Manufacturer: American Electromedics Corporation
13 Columbia Drive
Suite 5
Amherst, NH 03031

Submitted By: Ferguson Medical
Consultant to American Electromedics Corporation

B. Contact Information: Phone: (603) 880-6300
FAX: (603) 880-8977

C. Classification Name: Auditory Impedance Tester, and Audiometer

Common/usual Name: Tympanometer/Audiometer

Proprietary Name: American Electromedics Quik Tymp 2 (QT2) Tympanometer/Audiometer With Integral Printer

D. Classification Number: 77ETY and 77EWO

E. Substantial Equivalence: Race Car Tympanometer With Audiometer and Quik Tymp2, and Quik Tymp1, American Electromedics Corporation (K970279)

F. Device Description: The American Electromedics Quik Tymp 2 (QT2) Tympanometer/Audiometer With Integral Printer is a combination device which can be used as a tympanometer or as an audiometer.

G. Intended Use: The device is intended to be used in conducting hearing evaluations and assisting in the diagnosis of possible otologic disorders.

H. Technological Characteristics: The American Electromedics Quik Tymp 2 (QT2) Tympanometer/ Audiometer With Integral Printer is a combination device which can be used as a tympanometer or as an audiometer, and has a built-in printer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 1998

American Electromedics Corporation
c/o Ferguson Medical
Frank Ferguson
2581 California Park Drive, Suite 269
Chico, CA 95928

Re: K983048
American Electromedics
Quik Tymp 2 (QT2) Tympanometer/Audiometer
with Integral Printer
Dated: August 1, 1998
Received: September 1, 1998
Regulatory class: II
21 CFR 874.1050/Procode: 77 EWO
21 CFR 874.1090/Procode: 77 ETY

Dear Mr. Ferguson:

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 requirements, 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If known):

Device Name: American Electromedics Quik Tymp 2 (QT2) Tympanometer/ Audiometer With Integral Printer

Indications For Use:

The American Electromedics Quik Tymp 2 (QT2) Tympanometer/Audiometer With Integral Printer is intended to be used in conducting hearing evaluations and assisting in the diagnosis of possible otologic disorders.

(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 Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983048

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

(Optional Format 1-2-96)