

NOV 17 1988

K983046

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
Common/usual Name: Tympanometer
Proprietary Name: American Electromedics Race Car
Tympanometer With Integral Printer
- D. Classification Number: 77ETY
- E. Substantial Equivalence: Race Car Tympanometer,
American Electromedics Corporation (K955289)
- F. Device Description: The American Electromedics Race Car
Tympanometer With Integral Printer is an impedance
tympanometer.
- 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 Race Car Tympanometer With Integral
Printer is an impedance tympanometer which has a
built-in printer.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 17 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K983046
American Electromedics
Race Car Tympanometer with Integral Printer
Dated: August 1, 1998
Received: September 1, 1998
Regulatory class: II
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):

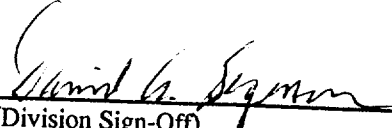
Device Name: American Electromedics Race Car Tympanometer
With Integral Printer

Indications For Use:

The American Electromedics Race Car Tympanometer
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 K983046

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)