4/12/99

K990813

EXHIBIT 1

General Information

a) Trade name /Proprietary Name: REHCOR™

b) Common name /Usual Name: Exercise Bicycle

c) Establishment registration number: ElectraMed will register (as initial importer) prior to marketing the device. The manufacturing company is FDA registered, number: 9019791

d) Address of manufacturer:

Lode B.V. Medical Technology.
Zernikepark 16
9747 AN Groningen
The Netherlands
Tel. 011-31-(0) 50-5712811
Fax 011-31-(0) 50-5716746

e) Device class: Class II per Regulation 890.5360, Measuring exercise equipment

Classification Name/Product Code: Measuring exercise equipment , Product code ISD

f) New or Modification: This notification is for a new device for the USA market. The product bears the CE mark and is legal for sale in Europe.

g) Predicate Devices (Substantial Equivalence): Lode Model Corival Ergometer, K851097

h) 513/514 Compliance (Performance Standard): None established under section 514. Complies with IEC 60601-1 Medical Electrical Equipment, Part 1: General requirements for safety,. 1. Collateral standard: Safety requirements for medical electrical systems and ISO 9001/EN 46001 Standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 1999

Daniel Kamm, P.E.
Kamm & Associates
Representing Electramed Corporation
P.O. Box 7007
Deerfield, Illinois 60015

Re: K990813
Trade Name: REHCOR™
Regulatory Class: II
Product Code: ISD
Dated: March 10, 1999
Received: March 11, 1999

Dear Mr. Kamm:

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 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) 594-4659. 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number_____

Device Name: Rehcor™

Indications for Use: Useful for physiotherapy in redevelopment of muscles or for restoration of motion to joints or for use as an adjunct treatment for obesity. The bicycle would be Class I exempt when sold without measuring capability but is available with ECG and/or blood pressure measuring options thus making it Class II, not exempt. The unit's workload can be controlled by an RS-232 input for connection to ECG stress test systems (supplied by other manufacturers)

_____ _____ _____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990863