AUG 13 2000

EISCHO, Inc. Intermittent Compression Boot
Premarket Notification
Summary Of Data

K991921

1. Submitter:

Clem Eischen
Owner
EISCHO, Inc.
1232 S.E. 282 Ave.
Grisham, OR 97080
Tel: (503) 2232
Fax: (503) 2232

2. Device Name

2.1	Classification:	Panel 74, Class II, 890.5650
2.2	Common/Usual Name:	Power Inflatable Tube Messager
2.3	Proprietary Name:	Intermittent Compression Boot

3. Predicate Device:

3.1 EISCO, Inc.'s Intermittent Compression Boot for professional use, K964957

4. Intended Use:

The EISCHO Intermittent compression Boot is intended for medical purposes, such as to relieve minor aches and pains and to increase circulation in the patient's lower limbs. It simulates kneading and stroking of tissues by using an inflatable pressure cuff. The boot is not life sustaining is not implanted and does not use software. It is constructed of plastic that is designed for use over the lower extremity. It appears as an inflated boot. There are no toxicology implications. It is not sterile and is intended for the use of one person. The device is for home, hospital or clinical use. There are no drug or biological components. See also exhibit 6, product labels, for indications for use.

5. Device Description:

This device is an inflatable garment or boot that is intended for use on patients' lower limbs. It consists of two chambers. The upper chamber envelops the lower extremity and the lower chamber is located under the foot.

The interior panel has been sealed onto the exterior panel. When pressure is applied to the lower chamber by the patient's foot, air moves from the lower chamber to the upper chamber through the air passageways shaded in blue.

The boot is placed on the patient and then inflated by attaching a hand pump to the port at the top of the boot. The boot is then inflated by means of the patient placing pressure on the foot..

At this point, the pressure in the upper chamber increases which causes a compression of the limb. When the patient lifts his/her foot, the air passes from the upper chamber to inflate the

lower chamber, which causes the overall boot pressure to return to nominal pressure. The pressure may be applied while walking, standing, sitting or lying.

The patient repeats this process until the therapy session is completed. To deflate the boot, the patient presses inward on the valve stem with his/her finger or uses the cap that is attached to the valve. The deflated boot is then easily removed.

6. Substantial Equivalency Comparisons:

The comparison of EISCHO's Intermittent Compression Boot for over the counter use and EISCHO's Intermittent Compression Boot for professional use K964957 are the same The intermittent compression boot for over the counter use is indicated for first aid use on minor sports injuries and the intermittent compression boot for professional use is indicated for post phlebitis syndrome; swelling of foot, ankle and lower leg due to total knee replacement; bruising, swollen knee and ankle; and gravitational edema after cast removal.

7. Conclusions:

Comparison of EISCHO's Intermittent Compression Boot for over the counter use and EISCHO's Intermittent Compression Boot for professional use indicates that they are substantially equivalent. The intermittent compression boot for over the counter use is use for first aid minor injuries. This poses no new safety of functional issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1999

Mr. Clem Eischen
President/Sales
Eischco, Incorporated
1232 S.E. 282nd Avenue
Gresham, Oregon 97080

Re: K991921
Trade Name: Intermittent Compression Boot for OTC
Regulatory Class: II
Product Code: IRP
Dated: May 28, 1999
Received: June 7, 1999

Dear Mr. Eischen:

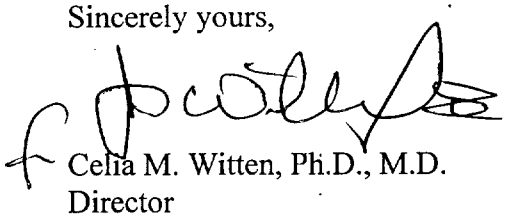
We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 control provisions of the Act. The general control 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

Indications for Use Statement

510(k) Number (if known): Unknown K991921

Device Name: Intermittent Compression Boot For Over The Counter Use

Indications For Use:

The EISCHO Intermittent compression Boot is intended for first aid treatment of minor sportrs injuries. It is intended to relieve minor aches and pains and to increase circulation in the patient's lower limbs. It simulates kneading and stroking of tissues by using an inflatable pressure cuff.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The-Counter USE** X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991921