DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Peter A. Sullivan
Engineer
The Prometheus Group
2 Mallards Cove
Duxbury, Massachusetts 02332

DEC 17 1997

Re: K973537
Trade Name: Pathway TR-10, TR-10C, TR-20, TR20C
Regulatory Class: II
Product Code: HCC
Dated: September 16, 1997
Received: September 18, 1997

Dear Mr. Sullivan:

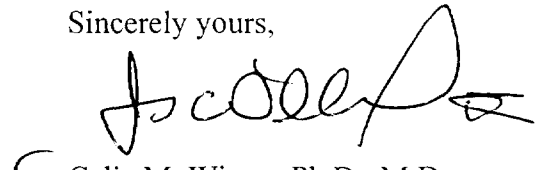
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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) 594-4595. Additionally, for questions on the promotion and advertising of your devices, 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

STATEMENT of INDICATIONS for USE

510(k) Number (if known): K973537
Device Name: Pathway TR-10, TR-10C, TR-20, TR20C

Indications for Use:

Surface electromyography is a safe and effective technique for relaxation training and muscle re-education.

Using internal perineometer electrodes such as the PerryVaginal:
EMG biofeedback is a safe and effective technique for the assessment and treatment of pelvic floor dysfunction, monitoring the performance of Kegel exercises. The pelvic floor muscles include the Levator Ani group as well as the pubococcygeus (PC), ileococcygeus, and coccygeus. These are skeletal muscles which respond to re-education, strengthening, endurance building, and relaxation.

Conditions that can be assessed or treated using this technique include: stress incontinence, mixed incontinence, and urge incontinence.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973537

Prescription Use X OR Over-the-Counter Use
(Per 21 CFR 801.109)