

The Prometheus Group

80 Bow Street Portsmouth, NH 03801
Phone: 603-431-5121 Fax: 603-431-0650

DEC 22 1997

510(k) SUMMARY
Safety and Effectiveness Summary

Pathway Vaginal/Rectal Perineometer Probe

Submitted by:

Peter A Sullivan
80 Bow Street
Portsmouth, NH 03801
Phone: 603-431-5121
Fax: 603-431-0650

Contact Person:

Peter A Sullivan

Date Submitted:

October 23, 1997

NAME OF DEVICE

Trade name: Pathway Vaginal/Rectal Perineometer Probe

Common name: Perineometer Probe

Classification name: Perineometer (per 21 CFR section 884.1425)

IDENTIFICATION OF PREDICATE DEVICE

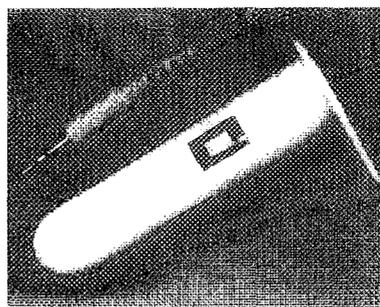
The device to which we claim substantial equivalence is the Perrymeter Vaginal Perineometer Probe and Perrymeter Anal Perineometer Probe 510(k) number K911190/A. The Perrymeter probes are also single-user plastic probes with three metal electrode contacts.

DESCRIPTION OF DEVICE

The Pathway Vaginal/Rectal Perineometer Probe is an EMG perineometer probe used to monitor the pelvic floor muscles for the treatment of incontinence. This probe is connected to a surface EMG device to provide Bio-feedback to the patient. This allows the patient to monitor their pelvic muscle activity which is otherwise difficult due to the anatomical location of the pelvic floor muscles.

The Pathway Vaginal/Rectal Perineometer Probe is a single-user plastic probe with three metal electrode contacts. The patient inserts the probe into the vagina or rectum and uses a surface EMG instrument to monitor the muscle activity during contraction and relaxation of the pelvic floor muscles. The aim is to improve the strength and control of the pelvic floor muscles.

Pathway Vaginal/Rectal Perineometer Probe



INTENDED USE

Indications For Use:

- * Urinary Incontinence : Stress, Urge and Mixed Incontinence
- * Fecal Incontinence
- * Neuromuscular Reeducation

**SUMMARY OF TECHNICAL CHARACTERISTIC COMPARISON TO
PREDICATE DEVICE**

	<u>Pathway Probe</u>	<u>Perrymeter Probe</u>
Single-User Perineometer Probe	Yes	Yes
Plastic Probe with Metal Contacts	Yes	Yes
Three Electrode Contacts	Yes	Yes
Two Active, One Ground Contact	Yes	Yes
Shielded Cable	Yes	Yes
1/8" Stereo Plug Connector	Yes	Yes
Proper Orientation for Best Use	Yes	Yes
Urinary or Fecal Incontinence	Yes	Yes
Vaginal Use	Yes	Yes (Perry Vaginal)
Rectal Use	Yes	Yes (Perry Anal)
Clinic, Hospital & Home Use	Yes	Yes
Bulb at Tip of Probe to Assist Retention of Probe During Use	No	Yes
Light Weight to Assist Retention of Probe During Use	Yes	No
Bulb at Base of Probe for Insertion/Removal and Control Insertion Depth	No	Yes
Tab at Base of Probe for Insertion/Removal and Control Insertion Depth	Yes	No
Arrow on Bottom of Probe for Orientation	No	Yes
Tab at Base of Probe for Orientation	Yes	No

NON-CLINICAL PERFORMANCE DATA

A series of bench tests were performed using the Pathway Vaginal/Rectal Perineometer Probe to show the probe accurately measured EMG signals and was substantially equivalent to the predicate device. The Pathway Vaginal/Rectal Perineometer Probe was used to measure signals spanning the input range of the EMG device. A matrix of different frequencies and amplitudes was measured by the probe and the resulting readings compared to the input signals. The same bench tests were performed on the predicate device.

The bench tests show the Pathway Vaginal/Rectal Perineometer Probe accurately measures EMG signals. The bench tests also show that the Pathway Vaginal/Rectal Perineometer Probe performs similarly to the predicate device. The readings obtained using the Pathway Vaginal/Rectal Perineometer Probe were generally within 5% of the readings obtained using the predicate device.

CLINICAL PERFORMANCE DATA

The Pathway Vaginal/Rectal Perineometer Probe was used in a series of simple clinical tests to show the probe accurately measured EMG signals and was equivalent to the predicate device. A number of Male and Female subjects were instructed to perform a series of contractions and relaxations using the Pathway Vaginal/Rectal Perineometer Probe and also using the predicate device. These sessions were recorded using a personal computer.

The clinical tests show the Pathway Vaginal/Rectal Perineometer Probe accurately monitors the pelvic floor muscles. The clinical tests also show the Pathway Vaginal/Rectal Perineometer Probe performs similarly to the predicate device. The Pathway Vaginal/Rectal Perineometer Probe had an overall ratio between EMG contraction levels and EMG relaxation levels of 5.4:1 and the predicate device had an overall ratio between EMG contraction levels and EMG relaxation levels of 5.1:1.

BIOCOMPATIBILITY TESTING

The Pathway Vaginal/Rectal Perineometer Probe has been laboratory tested for the safety of the materials. The Pathway Vaginal/Rectal Perineometer Probes were found to be safe under the standards required for each test. A listing of each performed test and the result:

Test	Result
SKIN SENSITIZATION KLIGMAN MAXIMIZATION TEST Date of Test: 9/25/97	0% Sensitization; Weak allergenic potential
SYSTEMIC INJECTION TEST Date of Test: 9/9/97	Negative; No significant biological reaction
L929 MEM ELUTION TEST Date of Test: 8/21/97	Non-cytotoxic
PYROGEN TEST (Material Mediated) Date of Test: 9/3/97	Non-pyrogenic
PRIMARY VAGINAL TEST - REPEATED EXPOSURE Date of Test: 10/14/97	Minimal irritant
RECTAL IRRITATION TEST - REPEATED EXPOSURE Date of Test: 9/26/97	Non-irritant

CONCLUSION

The Pathway Vaginal/Rectal Perineometer Probe is safe and effective for its intended use. The Pathway Vaginal/Rectal Perineometer Probe is substantially equivalent to the predicate device.

END OF 510(k) SUMMARY



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1997

Mr. Richard Horton
Vice President of Engineering
The Prometheus Group
2 Mallards Cove
Duxbury, Massachusetts 02332

Re: K974036
Pathway Vaginal/Rectal Perineometer Probe
Dated: October 23, 1997
Received: October 24, 1997
Regulatory class: II
21 CFR §884.1425/Product code: 85 HIR

Dear Mr. Horton:

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) 594-4613. 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/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

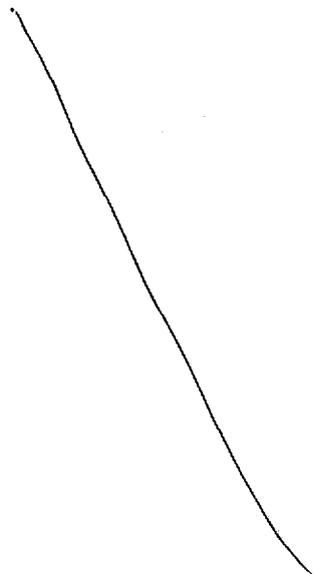
SECTION 2
STATEMENT of INDICATIONS for USE

510(k) Number (if known): _____
Device Name: Pathway Vaginal/Rectal Perineometer Probe

Indications for Use:

Indications For Use

- * **Urinary Incontinence : Stress, Urge and Mixed Incontinence**
- * **Fecal Incontinence**
- * **Neuromuscular Reeducation**



Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Matheny /
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974036

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