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The Prometheus Group

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FEB 22 2000

510(k) SUMMARY
Safety and Effectiveness Summary

Pathway Vaginal EMG/Stimulation Perineometer Sensor
Pathway Anal EMG/Stimulation Perineometer Sensor

Submitted by:

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Contact Person:

Richard Horton

Date Submitted:

Feb 4, 2000

A-11

NAME OF DEVICE

Trade name: Pathway Vaginal EMG/Stimulation Perineometer Sensor
Pathway Anal EMG/Stimulation Perineometer Sensor

Common name: Perineometer Sensor

Classification name: Perineometer (per 21 CFR section 884.1425)

IDENTIFICATION OF PREDICATE DEVICE

The device to which we claim substantial equivalence is the Pathway Vaginal/Rectal EMG Perineometer Sensor 510(k) number K974036, the InCare Vaginal EMG/Stimulation Perineometer Sensor and the InCare Anal EMG/Stimulation Perineometer Sensor 510(k) numbers K891773 and K930530. The Pathway Vaginal/Rectal EMG Perineometer Sensor, the InCare Vaginal EMG/Stimulation Sensor and the InCare Anal EMG/Stimulation Sensor are also single-user plastic sensors with stainless steel electrode contacts.

DESCRIPTION OF DEVICE

The Pathway Vaginal EMG/Stimulation Perineometer Sensor and the Pathway Anal EMG/Stimulation Perineometer Sensor are EMG OR Stimulation perineometer sensors used to monitor OR stimulate the pelvic floor muscles for the treatment of incontinence. This sensor 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. This sensor is connected to a stimulator device to provide stimulation to the patient. This assists the patient with muscle contractions.

The Pathway Vaginal EMG/Stimulation Perineometer Sensor and the Pathway Anal EMG/Stimulation Perineometer Sensor are single-user plastic sensors with stainless steel electrode contacts. The patient inserts the sensor 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 patient can instead use a stimulator to electrically stimulate the pelvic floor muscles to assist the contraction. The aim is to improve the strength and control of the pelvic floor muscles.

INTENDED USE

Indications For Use:

- * **Urinary Incontinence : Stress, Urge and Mixed Incontinence**
- * **Neuromuscular Reeducation**
- * **Fecal Incontinence (EMG use only)**

SUMMARY OF TECHNICAL CHARACTERISTIC COMPARISON TO PREDICATE DEVICE

Feature	Pathway Vaginal	Pathway Anal	Pathway Vag/Rect	InCare Vaginal	InCare Anal
Single-User Perineometer Sensor	Yes	Yes	Yes	Yes	Yes
Plastic Sensor with Metal Contacts	Yes	Yes	Yes	Yes	Yes
Three Electrode Contacts	Yes	Yes	Yes	No	No
Two Active, One Ground Contact	Yes	Yes	Yes	No	No
Separate Ground Connection for EMG	No	No	No	Yes	Yes
Shielded Cable	Yes	Yes	Yes	Yes	Yes
Safety 1/8" Stereo Plug Connector	Yes	Yes	Yes	No	No
1/8" Stereo Plug Connector	No	No	No	Yes	Yes
Urinary Incontinence	Yes	Yes	Yes	Yes	Yes
Fecal Incontinence (EMG use only)	Yes	Yes	Yes	No	No
Vaginal Use	Yes	No	Yes	Yes	No
Rectal Use	No	Yes	Yes	No	Yes
Clinic, Hospital & Home Use	Yes	Yes	Yes	Yes	Yes
Bulb at Tip of Sensor to Assist Retention of Sensor During Use	Yes	Yes	No	No	Yes
Tab at Base of Sensor for Insertion/Removal and Control Insertion Depth	Yes	Yes	Yes	No	No
Arrow on Bottom of Sensor for Orientation	Yes	Yes	No	No	No
Tab at Base of Sensor for Orientation	Yes	Yes	Yes	No	No
Use for EMG measurement	Yes	Yes	Yes	Yes	Yes
Use for Stimulation	Yes	Yes	No	Yes	Yes
Overall Length	2.9"	2.4"	2.9"	4.3"	2.3"
Sensing Diameter	.70"	.50"	.73"	1.0"	.47"

NON-CLINICAL PERFORMANCE DATA

A series of bench tests were performed using the Pathway Vaginal EMG/Stimulation Perineometer Sensor and the Pathway Anal EMG/Stimulation Perineometer Sensor to show the sensor accurately measures EMG signals and is substantially equivalent to the predicate device. The sensors were used to measure a known input signal and the measured value was compared to the known input signal to check the accuracy of the measurement. The same bench tests were performed on the predicate device.

The bench tests show the Pathway Vaginal EMG/Stimulation Perineometer Sensor and the Pathway Anal EMG/Stimulation Perineometer Sensor accurately measure EMG signals. The bench tests also show that the Pathway Vaginal EMG/Stimulation Perineometer Sensor and the Pathway Anal EMG/Stimulation Perineometer Sensor perform similarly to the predicate device. The readings obtained using the Pathway Vaginal EMG/Stimulation Perineometer Sensor and the

Pathway Anal EMG/Stimulation Perineometer Sensor were generally within 2% of the readings obtained using the predicate device.

CLINICAL PERFORMANCE DATA

The Pathway Vaginal EMG/Stimulation Perineometer Sensor and the Pathway Anal EMG/Stimulation Perineometer Sensor were used in a series of simple clinical tests to show the sensors accurately measured EMG signals and provided stimulation and to show they were equivalent to the predicate device. A test subject was instructed to perform a series of contractions and relaxations using the Pathway Vaginal EMG/Stimulation Perineometer Sensor, the Pathway Anal EMG/Stimulation Perineometer Sensor, and also the predicate device. These EMG sessions were recorded using a personal computer. The test subject also used a variety of stimulators with the sensors to generate contractions. The resulting contractions were monitored using a pressure perineometer sensor in the alternate placement (vagina or rectum) to compare the performance of the sensors.

The clinical tests show the Pathway Vaginal EMG/Stimulation Perineometer Sensor and the Pathway Anal EMG/Stimulation Perineometer Sensor accurately monitor and provide stimulation to the pelvic floor muscles. The clinical tests also show the Pathway Vaginal EMG/Stimulation Perineometer Sensor and the Pathway Anal EMG/Stimulation Perineometer Sensor perform similarly to the predicate device

BIOCOMPATIBILITY TESTING

The Pathway Vaginal EMG/Stimulation Perineometer Sensor and the Pathway Anal EMG/Stimulation Perineometer Sensor have been laboratory tested for the safety of the materials. The Pathway Vaginal EMG/Stimulation Perineometer Sensor and the Pathway Anal EMG/Stimulation Perineometer Sensor 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

Non-irritant

Date of Test: 9/26/97

CONCLUSION

The Pathway Vaginal EMG/Stimulation Perineometer Sensor and the Pathway Anal EMG/Stimulation Perineometer Sensor are safe and effective for their intended use. The Pathway Vaginal EMG/Stimulation Perineometer Sensor and the Pathway Anal EMG/Stimulation Perineometer Sensor are substantially equivalent to the predicate device.

END OF 510(k) SUMMARY



FEB 22 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. Richard Horton
The Prometheus Group
2 Mallards Cove
Duxbury, MA 02332Re: K993976
Pathway Vaginal EMG/Stimulation
Perineometer Sensor and Pathway
Anal EMG/Stimulation Perineometer
Sensor
Dated: February 4, 2000
Received: February 8, 2000
Regulatory Class: II
21 CFR §876.5320/Procode: 78 KPI
21 CFR §884.1425/Procode: 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 legally marketed predicate 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

