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Hollister

Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048-3781

Hollister Incorporated
Vaginal Stimulation/EMG Probe - Tampon

510(k) Summary

JUN 25 1997

1. Submitter's name, Address and Contact Person

Submitter
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Contact Person
Joseph S. Tokarz
Manager, Regulatory Affairs
Ph (847)680-2849
Fax (847)918-3860

Date Summary Prepared - April 24, 1997

2. Name of Device:

Vaginal Stimulation/EMG Probe - Tampon

3. Name of Predicate Device(s)

Vaginal Stimulation/EMG Probe, K891773 and K930530
Vaginal Stimulation/EMG Probe - Small K970602

4. Description of Device

Hollister Incorporated through it's InCare Division currently markets a vaginal 2-electrode Stimulation/EMG probe (K891773 and K930530) and a Small Vaginal Stimulation/EMG probe (K970602) as accessories to it's Pelvic Floor Therapy System product line. Therapy with these currently marketed probes, is normally performed with the patient in the supine position. Requests and comments from physicians and caregivers has indicated the need for a probe that will remain in place and allow the patient to perform normal activities, such as standing or bending during therapy. In response to these comments, Hollister has developed the vaginal 2-electrode stimulation/EMG probe - Tampon. The proposed probe uses the same identical raw material components and manufacturing process as the currently marketed devices. The proposed probe has a shorter overall length to help it remain in place while a patient is standing, bending, stooping or squatting during therapy.

5. Statement of Intended Use

The Vaginal Stimulation/EMG Probe - Tampon, is intended to provide electromyographic feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.

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6. Statement of Technological Characteristics of the Device

The proposed device is substantially equivalent to the predicate devices. The following is a chart comparing the devices.

Electrode Characteristics	**Vaginal Stimulation/ EMG Probe - Tampon**	**Vaginal Stimulation/ EMG Probe-Small**	**Vaginal Stimulation/ EMG Probe - Standard**
Number of Electrode	2-Stimulation/EMG	2-Stimulation/EMG	2-Stimulation/EMG
Usage Conditions	Reusable - single patient use	Reusable - single patient use	Reusable - single patient use
Electrode Orientation	Circular	Circular	Circular
Body Material	Acrylonitrile-Butadiene-Styrene copolymer (ABS)	Acrylonitrile-Butadiene-Styrene copolymer (ABS)	Acrylonitrile-Butadiene-Styrene copolymer (ABS)
Probe Length	2.3 inches nominal	4.8 inches nominal	4.8 inches nominal
Probe Diameter	0.841 inch nominal	0.750 inch nominal	1.0 inch nominal
Electrode Material	Stainless steel	Stainless steel	Stainless steel
Electrode Placement	Vaginal	Vaginal	Vaginal
Device Connector	Attached cord with 3.5 mm stereo phono plug	Attached cord with 3.5 mm stereo phono plug	Attached cord with 3.5 mm stereo phono plug
Contact Duration	Intermittent mucosal contact <30 min/session - Stim <1 hour/session - EMG not exceeding 1 hr combined Stim/EMG	Intermittent mucosal contact <30 min/session - Stim <1 hour/session - EMG not exceeding 1 hr combined Stim/EMG	Intermittent mucosal contact <30 min/session - Stim <1 hour/session - EMG not exceeding 1 hr combined Stim/EMG
Indications for Use	Electrical stimulation of the pelvic floor muscles for the treatment of urinary incontinence. EMG sensing of the pelvic floor muscles	Electrical stimulation of the pelvic floor muscles for the treatment of urinary incontinence. EMG sensing of the pelvic floor muscles	Electrical stimulation of the pelvic floor muscles for the treatment of urinary incontinence. EMG sensing of the pelvic floor muscles

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7. Biocompatibility

The biocompatibility of the Vaginal Stimulation/EMG Probe - Tampon, in nonsterilized configurations was assessed based on principles and guidelines established by various governmental and standard setting organizations, such as:

-- ISO 10993, International Standards Organization (ISO) Standard
-- General Program Memorandum #G95-1, United States FDA Office of Device Evaluation
-- United Stated Pharmacopeia (USP)

Material biocompatibility issues have been addressed based upon biomaterial history or in separate in vitro or in vivo laboratory evaluations using licensed commercial reference laboratories. Specific test methodology has been chosen, where appropriate, from test protocols established or recommended by the aforementioned agencies or organizations. Product use conditions have been mimicked in testing procedures where possible. These evaluations have been contracted either by Hollister or the suppliers of the materials.

Based upon the results of this assessment, the materials used to fabricate Vaginal Stimulation/EMG Probe - Tampon, are considered biocompatible and appropriate for their intended use.

8. Conclusion

Based upon the information presented above it is concluded that the proposed Vaginal Stimulation/EMG Probe - Tampon, is safe and effective for its intended use and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 1997

Mr. Joseph S. Tokarz
Manager, Regulatory Affairs
Hollister, Inc.
2000 Hollister Drive
Libertyville, Illinois 60048

Re: K971541
Vaginal Stimulation/EMG Probe - Tampon
Dated: April 24, 1997
Received: April 28, 1997
Regulatory class: II
21 CFR §876.5320/Product code: 78 KPI
21 CFR §884.1425/Product code: 85 HIR

Dear Mr. Tokarz:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4616. 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

Hollister Incorporated
Vaginal Stimulation/EMG Probe - Tampon

a.

Statement of Intended Use

510(k) Number (if Known): K971541

Device Name: Vaginal Stimulation/EMG Probe - Tampon

Intended Use:

The Vaginal Stimulation/EMG Probe - Tampon, is intended to provide electromyographic feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.

(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 ___

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Peter R. Nathan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971541