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Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048-3781

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Hollister Incorporated
Vaginal Stimulation/EMG Probe - Small

510(k) Summary

1. Submitter's name, Address and Contact Person

Submitter

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Contact Person

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Date Summary Prepared - February 13, 1997

2. Name of Device:

Vaginal Stimulation/EMG Probe - Small

3. Name of Predicate Device(s)

Vaginal Stimulation/EMG Probe, K891773

4. Description of Device

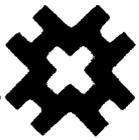
Hollister Incorporated through it's InCare Division currently markets a vaginal 2-electrode stimulation/EMG probe (K891773) as an accessory to it's Pelvic Floor Therapy System product line. Requests and comments from physicians and caregivers has indicated the need for a smaller diameter vaginal probe that would be used by patients that have a smaller vaginal anatomy and who cannot use the currently marketed vaginal probe. In response to these comments, Hollister has developed the vaginal 2-electrode stimulation/EMG probe - small. This probe uses the same identical raw material components and manufacturing process as the currently marketed device. The only difference is that the proposed probe has a smaller diameter to accommodate smaller vaginal anatomies.

5. Statement of Intended Use

The Vaginal Stimulation/EMG Probe - Small 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.

6. Statement of Technological Characteristics of the Device

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



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Comparison of the Vaginal Stimulation/EMG Probe-Small and Predicate device

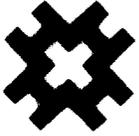
Electrode Characteristics	Vaginal Stimulation/EMG Probe-Small	Vaginal Stimulation/EMG Probe - Standard
Number of Electrode	2-Stimulation/EMG	2-Stimulation/EMG
Usage Conditions	Reusable - single patient use	Reusable - single patient use
Electrode Orientation	Circular	Circular
Body Material	Acrylonitrile-Butadiene-Styrene copolymer (ABS)	Acrylonitrile-Butadiene-Styrene copolymer (ABS)
Probe Length	4.8 inches nominal	4.8 inches nominal
Probe Diameter	0.750 inch nominal	1.0 inch nominal
Electrode Material	Stainless steel	Stainless steel
Electrode Placement	Vaginal	Vaginal
Device Connector	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 - stimulation <1 hour/session - biofeedback not exceeding 1 hr combined stimulation/biofeedback	Intermittent mucosal contact <30 min/session - stimulation <1 hour/session - biofeedback not exceeding 1 hr combined stimulation/biofeedback
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

7. Biocompatibility

The biocompatibility of the Vaginal Stimulation Probe, 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 States 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



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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 Probe - Small 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 - Small is safe and effective for its intended use and is substantially equivalent to the predicate device.