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K963222

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Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048-3781

Hollister Incorporated
Microgyn Plus Stimulation Device, K963222
Additional Information

510(k) Summary

1. Submitter's name, Address and Contact Person

Submitter

Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Contact Person

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Date Summary Prepared - August 14, 1996

2. Name of Device:

Hollister Microgyn Plus Stimulation Device

3. Name of Predicate Device(s)

- InCare Microgyn II Stimulation Device, K891773
- InCare PRS9300 Pelvic Floor Therapy System, K930530C
- Empi Innova Stimulation device, K910081/A

4. Description of Device

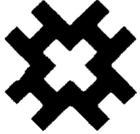
The Microgyn Plus Stimulation Device is intended to provide electrical stimulation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of urinary incontinence in women.

The Microgyn Plus is a battery powered device that delivers a regulated stimulus to the nerves and muscles of the pelvic floor. The stimulus is administered by attaching an anatomically shaped probe to the device and then inserting the probe into the patient's vagina or anus. When stimulation is delivered the body responds by contracting the muscles of the pelvic floor.

5. Statement of Intended Use

The Microgyn Plus Stimulation Device is intended to provide electrical stimulation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of urinary incontinence in women.

6. Statement of Technological Characteristics of the Device



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Microgyn Plus Stimulation Device

anatomically shaped probe to the device and then inserting the probe into the patients vagina or anus. The Microgyn Plus provides a balanced biphasic stimulation pulse. The pulse has a positive and negative phase such that the net charge applied to the patient is zero.

The Microgyn Plus is a current controlled device that provides an output that is adjustable from 0-60 milliamperes. The device also has the ability to select between three frequencies (20, 50, 100 Hz) depending on the frequency selected by the caregiver and the individual needs of the patient.

7. Conclusion

Based upon the information presented above it is concluded that the proposed Microgyn Plus Stimulation Device is safe and effective for its intended use and is substantially equivalent to the predicate device.