APR 1 2 2005

K050483
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Hollister Incorporated
evadri Bladder Control System

510(k) Summary

1. Sponsor's name, Address and Contact Person

Sponsor
Hollister Incorporated
2000 Hollister Drive
Libertyville IL. 60048

Contact Person
Joseph S. Tokarz
Director, Regulatory Affairs
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048
Ph: (847) 680-2849
Fax: (847) 918-3860

Date Summary Prepared – February 21, 2005

2. Name of Device:

evadri Bladder Control System

3. Name of Predicate Device(s)

- InCare pelvic Floor Therapy System (K9305530/c, K961872, K974048,and K013612)
- Pathway CTS 2000 pelvic Floor Training System (K001515 and K023906)

4. Description of Device

The evadri Bladder Control System is an office based instrument that is intended to be used by physicians, nurses, nurse clinicians, and physiotherapists in an office, clinic, or hospital. The evadri office unit is intended to provide electromyography or pressure biofeedback from pelvic musculature. The device also provides electrical stimulation to the pelvic musculature. The modalities of biofeedback and electrical stimulation are intended for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of incontinence.

5. Statement of Intended Use

The evadri Bladder Control System is intended to provide electrical stimulation or electromyographic or pressure biofeedback for the treatment of urinary and fecal (electromyographic biofeedback) incontinence.

6. Statement of Technological Characteristics of the Device

Stimulation:

Frequency (Hz)	10, 12.5, 20, 50, 100, 200
Pulse width (msec)	0.3, 1
Pulse Type	Balanced, biphasic, no dc component.
Pulse Amplitude (VDC)	0-30, 1% or 5% increments
ON period (seconds)	1-80 in 1 second increments
Off period (seconds)	0-80 in 1 second increments
Session Duration (minutes)	1-30 in 1 minute increments

Hollister Incorporated
Evadri System

Biofeedback:

Measurement channels	Adjustable,2 channels of EMG, 2 channels of pressure or combination of EMG and pressure.
EMG Sensitivity (micro volts)	0-5, 0-10, 0-25, 0-50, 0-100, 0-250, 0-500
EMG bandwidth	20-500Hz (channel 1), 100-500Hz (channel 2)
EMG signal processing	Root Mean Squared (RMS)
EMG detection	Bipolar
Pressure sensitivity (cmH_2O)	0-10, 0-25, 0-50, 0-100, and 0-350
Work periods (seconds)	1-80 in 1 second increments
Rest periods (seconds)	0-80 in 1 second increments
Session Duration (minutes)	1-60 minutes in 1 minute increments

Instrumentation Unit:

Power	AC to DC power adapter, isolated, 115/230 VAC switch able input, 6VDC output
Power rating	20VA
Overall current protection	3 ampere fuse
Overall Dimensions	100 x 70 x 130mm
Approximate weight	8lbs

7. Conclusion

Based upon the information presented within this pre-market notification it is concluded that the evadri Bladder Control System is safe and effective for its intended use and the device is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2005

Mr. Joseph S. Tokarz
Director Regulatory Affairs
Hollister Incorporated
2000 Hollister Drive
LIBERTYVILLE IL 60048-3781

Re: K050483
Trade/Device Name: evedri Bladder Control System
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: KPI
Dated: February 21, 2005
Received: February 24, 2005

Dear Mr. Tokarz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K050483

Hollister Incorporated
evadri Bladder Control System

Statement of Intended Use

510(k) Number (if Known):
Device Name: evadri Bladder Control System

Intended Use:
The evadri Bladder Control System is intended to provide electrical stimulation or electromyographic or pressure biofeedback for the treatment of urinary and fecal (electromyographic biofeedback) 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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050483