

3/25/99

Hollister Incorporated  
2000 Hollister Drive  
Libertyville, Illinois 60048-3781

Telephone: 847.680.1000  
Facsimile: 847.918.3860

Hollister Incorporated  
Anal Stimulation/EMG Probe - w/Stop

K990456



## 510(k) Summary

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### 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 - February 9, 1999

### 2. Name of Device:

Anal Stimulation/EMG Probe - w/Stop

### 3. Name of Predicate Device(s)

Anal Stimulation/EMG Probe, K891773 and K930530

### 4. Description of Device

Hollister Incorporated through it's InCare Division currently markets an Anal 2-electrode Stimulation/EMG Probe (K891773 and K930530) as an accessories to it's Pelvic Floor Therapy System product line. The proposed probe uses the same identical raw material components and manufacturing process as the currently marketed predicate devices.

### 5. Statement of Intended Use

The Anal Stimulation/EMG Probe - w/Stop, 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.

<b>Electrode Characteristics</b>	<b>Anal Stimulation/EMG Probe - w/Stop</b>	<b>Anal Stimulation/EMG Probe - Standard</b>
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	2.349 inches nominal	3.45 inches nominal
Probe Diameter (between electrode)	0.453 inch nominal	0.394 inch nominal
Electrode Material	Stainless Steel	Stainless Steel
Electrode Placement	Anal	Anal
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 - 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

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**7. Biocompatibility**

The biocompatibility of the Anal Stimulation/EMG Probe - w/Stop, 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 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 Anal Stimulation/EMG Probe - w/Stop, is safe and effective for its intended use and is substantially equivalent to the predicate device.

**8. Conclusion**

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



MAR 25 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Mr. Joseph S. Tokarz  
Manager, Regulatory Affairs  
Hollister Incorporated  
2000 Hollister Drive  
Libertyville, IL 60048-3781Re: K990456  
Anal Stimulation/EMG Probe with Stop  
Dated: February 9, 1999  
Received: February 12, 1999  
Regulatory Class: II  
21 CFR 876.5320/Procode: 78 KPI  
21 CFR 884.1425/Procode: 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 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

Hollister Incorporated  
Anal Stimulation/EMG Probe - w/Stop

a.

**Statement of Intended Use**

510(k) Number (if known):           K990456          

Device Name:           Anal Stimulation/EMG Probe - w/Stop          

**Intended Use:**

The Anal Stimulation/EMG Probe - w/Stop, 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   
(Per 21 CFR 801.109)

OR

Over-the-Counter-Use

(Optional Format 1-2-96)

*David M. [Signature]*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number           K990456