



DEC 23 1997

K974048

Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048-3781

P103

InCare Pelvic Floor Therapy System with Desktop Computer

Safety and Effectiveness Summary

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 - October 21, 1997

2. Name of Device:

InCare Pelvic Floor Therapy System with Desktop Computer

3. Name of Predicate Device(s)

Hollister PRS9300 Pelvic Floor Therapy System, K961872

4. Description of Device

The InCare Pelvic Floor Therapy System with Desktop Computer is an office based instrument that is intended to be used by physicians, nurses, nurse clinicians, and physiotherapists in a physicians office, clinic, or hospital for the purpose of providing electromyographic or pressure biofeedback from pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control for the treatment of urinary incontinence. The InCare Pelvic Floor Therapy System also provides electrical stimulation capabilities for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of urinary incontinence.

The premarket notification is being submitted to the Agency to include the electrical stimulation parameter of 200 Hz to the existing InCare Pelvic Floor Therapy System with Desktop Computer, K961872.

5. Statement of Intended Use

The biofeedback components of the InCare Pelvic Floor Therapy System with Desktop Computer are intended to provide electromyographic or pressure biofeedback from pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control for the treatment of urinary incontinence.

The electrical stimulation component of the InCare Pelvic Floor Therapy System with Desktop Computer provides stimulation capabilities for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of urinary incontinence.



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InCare Pelvic Floor Therapy System with Desktop Computer

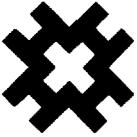
6. Statement of Technological Characteristics of the Device

• The proposed device and the predicate device, K961872 are substantially equivalent based upon the following:

1. Intended Use of the two devices are identical.
2. The proposed device and the predicate device, K961872 utilizes the exact same instrumentation unit. The Instrumentation Unit controls features and functions that are “patient treatment actions.”
3. The proposed device and the predicate device, K961872 utilizes the same software for the “data manipulation and presentation” activities associated with the personal computer and the “patient therapy” actions associated with the Instrumentation Unit.
4. The proposed device differs from the predicate device, K961872 in one aspect only. The proposed device has the additional stimulation parameter of 200 Hz.

• A chart showing the differences and similarities of the InCare Pelvic Floor Therapy System with Desktop Computer and the predicate device follows:

	Proposed Device	Predicate Device K961872
Stimulation Characteristics		
Intended Use	Treatment of Urinary Incontinence	Treatment of Urinary Incontinence
Computer Type	Desktop Computer	Desktop Computer
Output (nominal)	0-30 VDC	0-30 VDC
Waveform	Square, Symmetrical, Balanced, Biphasic	Square, Symmetrical, Balanced, Biphasic
charge/pulse at 500Ω	60 μC/phase; net charge/pulse = 0	60 μC/phase; net charge/pulse = 0
Frequency	12.5, 20, 50, 100, 200 Hz	12.5, 20, 50, 100 Hz
Peak Pulse Intensity	30 VDC	30 VDC
Pulse width	0.3, 1 ms	0.3, 1 ms
Ramps	20%, 40%, 60%, 80%, 100% of “ON” time (no down ramping)	20%, 40%, 60%, 80%, 100% of “ON” time (no down ramping)
Duty Cycle	On (sec): 1-80 in 1 sec increments Off (sec): 0 - 80 in 1 sec increments	On (sec): 1-80 in 1 sec increments Off (sec): 0 - 80 in 1 sec increments
Session Duration (min)	0-30, 1 minute increments	0-30, 1 minute increments
Programmable Features	NONE BY PATIENT By physician: Pulse width, Frequency, Duty cycle, Session length	NONE BY PATIENT By physician: Pulse width, Frequency, Duty cycle, Session length
Current Density Conditions: Full output setting, 100Hz, 1ms pulse width at 500 ohms (nominal)	Probe 9595 - 0.003 amperes/cm ² Probe 9596 - 0.018 amperes/cm ²	Probe 9595 - 0.003 amperes/cm ² Probe 9596 - 0.018 amperes/cm ²



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InCare Pelvic Floor Therapy System with Desktop Computer

	Proposed Device	Predicate Device K961872
Power Density Conditions: Full output setting, 100Hz, 1ms pulse width at 500 ohms (nominal)	Probe 9595 - 0.047 watts/cm ² Probe 9596 - 0.239 watts/cm ²	Probe 9595 - 0.047 watts/cm ² Probe 9596 - 0.239 watts/cm ²
EMI	**See Note below	**See Note below
Biofeedback Characteristics		
Intended Use	Treatment of Urinary Incontinence	Treatment of Urinary Incontinence
Measurement Channels	Adjustable, 2 channels EMG, 2 channels pressure, or combination EMG and pressure	Adjustable, 2 channels EMG, 2 channels pressure, or combination EMG and pressure
EMG Sensitivity (microvolts)	0-5, 0-10, 0-25, 0-50, 0-100, 0-250, 0-500	0-5, 0-10, 0-25, 0-50, 0-100, 0-250, 0-500
EMG Bandwidth	100-500 Hz	100-500 Hz
EMG Signal Processing	Root Mean Squared (RMS)	Root Mean Squared (RMS)
EMG Detection	Bipolar	Bipolar
Pressure Sensitivity (cm-H ₂ O)	0-10, 0-25, 0-50, 0-100	0-10, 0-25, 0-50, 0-100
Work Period (sec)	1-80 in 1 second increments	1-80 in 1 second increments
Rest Period (sec)	0-80 in 1 second increments	0-80 in 1 second increments
Session Duration (min)	1-60 in 1 minute increments	1-60 in 1 minute increments

****NOTE** IEC 601-1 (except Amendment 2:1995, new subclause 56.3c)
 IEC 601-1-1
 IEC 601-2-10 (except Paragraph 36)
 EN 60601-1-2/IEC 601-1-2
 EN 55011/CISPR 11
 EN60801-2/IEC 801-2, 3kv contact, 8kv air
 IEC 801-3, 3v/m, 1 khz
 IEC 801-4, 1kv
 IEC 801-5, 1kv

7. Conclusion

Based upon the information presented above it is concluded that the proposed InCare Pelvic Floor Therapy System with Desktop Computer is safe and effective for its intended use and is substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Joseph S. Tokarz
Manager, Regulatory Affairs
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Re: K974048
InCare Pelvic Floor Therapy System with Desktop
Computer
Dated: October 21, 1997
Received: October 24, 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 Current Good Manufacturing Practice requirement, 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/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

InCare Pelvic Floor Therapy System with Desktop Computer

b.

Statement of Intended Use

510(k) Number (if Known): _____

Device Name: InCare Pelvic Floor Therapy System with Desktop Computer

Indications For Use:

The biofeedback components of the InCare Pelvic Floor Therapy System with Desktop Computer are intended to provide electromyographic or pressure biofeedback from pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control for the treatment of urinary incontinence.

The electrical stimulation component of the InCare Pelvic Floor Therapy System with Desktop Computer provides stimulation capabilities for the purpose of rehabilitation of weak pelvic floor muscles for 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 _____

Robert J. Stalling
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

(Optional Format 1-2-96)

510(k) Number K974048