K970145

AUG 1 1 1997

biosearch®
MEDICAL PRODUCTS INC.

> 510(k) SUMMARY <

SAFETY & EFFECTIVENESS SUMMARY

PERINEOMETER & VAGINAL PROBE

Manufactured / Sold by:

Biosearch Medical Products, Inc.
35 Industrial Parkway
P.O. Box 1700
Somerville, NJ. 08876 {USA}

Telephone : 1-908-722-5000
Fax : 1-908-722-5024

Contact Person:

Martin Dyck

Martin Dyck

Vice President of Operations,
New Product Development Coordinator

7/15/97

date submitted

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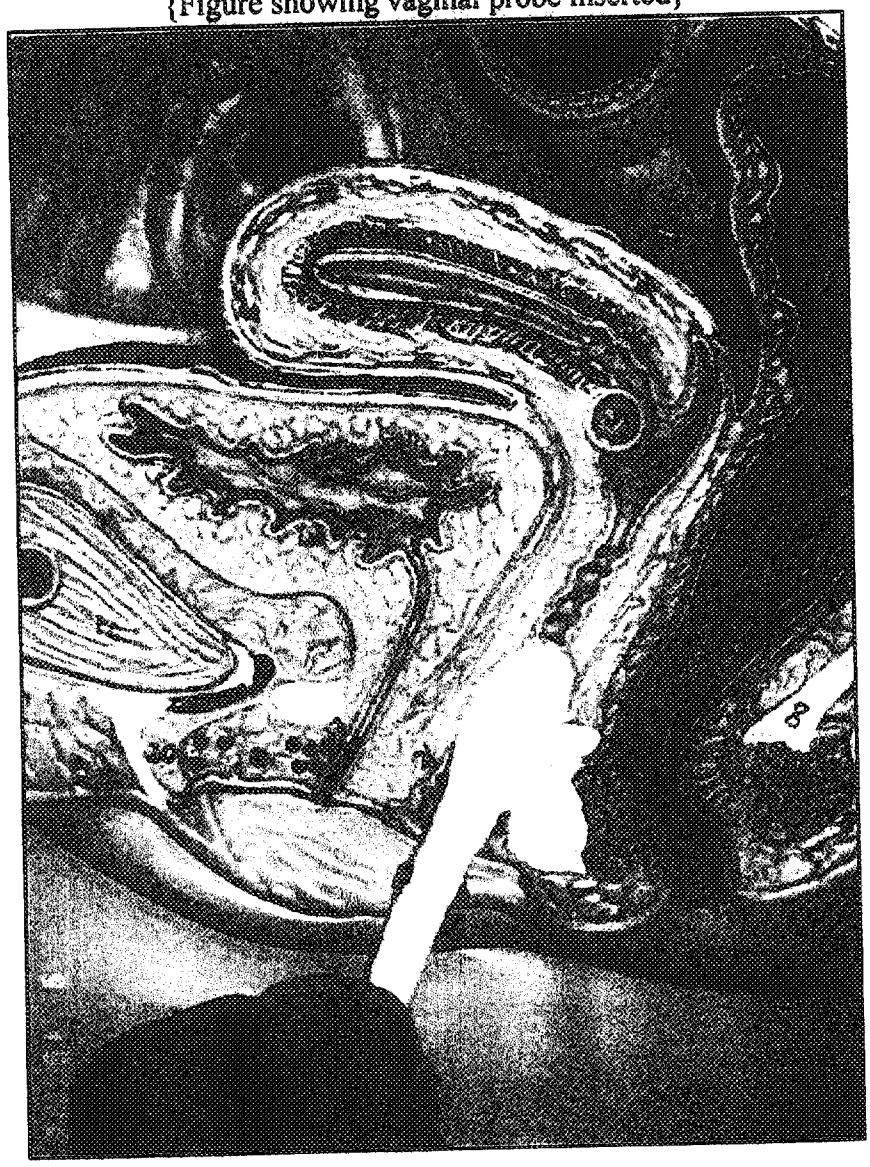
SAFETY & EFFECTIVENESS SUMMARY
Biosearch Medical Products, Inc.
PERINEOMETER & VAGINAL PROBE

INTENDED USE STATEMENT: The Perineometer (Biofeedback monitor) and vaginal probe are intended to be used to assist the patient in exercising her pelvic muscles (referred to Kegal exercises) which in the majority of cases lead to increased bladder control.

{Figure showing vaginal probe inserted}



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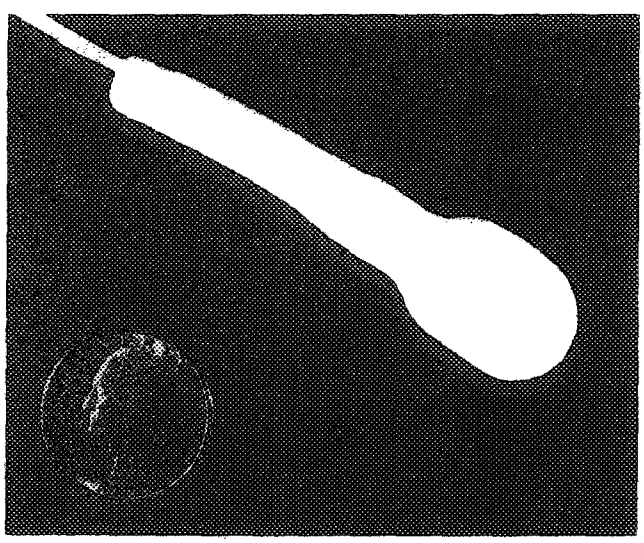
PERINEOMETER & VAGINAL PROBE

DESCRIPTION OF THE DEVICE:
The PERINEOMETER & VAGINAL PROBE , is a passive device which will allow the patient to visually monitor their Kegal exercise progress.

The **Vaginal probe** is a Single patient use only device comprised of a medical grade Silicone shaft with a silicone balloon (Inflatable to enlarge to accomodate various vaginal sizes.) and a polyurethane connector tube. The silicone balloon is mounted in such a way that when pressure is applied to it, air will be displaced through it's connector tubing. This air displacement is being monitored by the biofeedback monitor which will cause the LED lights to turn on in proportion to the pressure exerted. This probe is similar to the legally marketed probe via 510(k) numbers (k902843) and (k913736) except that in this case we are inflating the balloon to provide gentle pressure to the vaginal wall. This will allow the probe to be customized for the patients individual vaginal size.

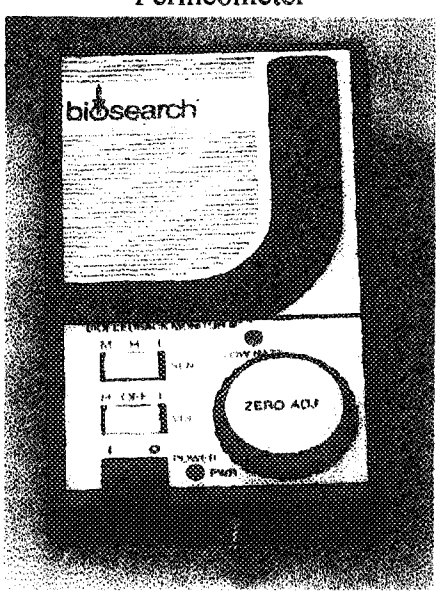
The **Perineometer (Biofeedback Monitor)** is powered by rechargeable batteries. To prevent a potential shock hazard this unit will not function while it is being recharged. The Perineometer is identical to the biofeedback monitor which had been 510(k) approved for use in fecal incontinence (k902843). Thus, in the case of this 510(k) submission, we only seek to expand its use for general Kegal exercises.

SYSTEM DESCRIPTION: The patient inserts the vaginal probe which is connected to the Perineometer. Once the probe is inserted the balloon is inflated until it provides gentle pressure to the vaginal wall. As the pelvic muscles expand and contract (Kegal exercises) the pressure in the probe changes and these pressure changes are converted into a visual signal on the Perineometer (biofeedback monitor). The visual signal on the Perineometer is a series of LEDs (lights) which provide the patient with a real time representation of pelvic muscle activity.



Vaginal Probe

Perineometer



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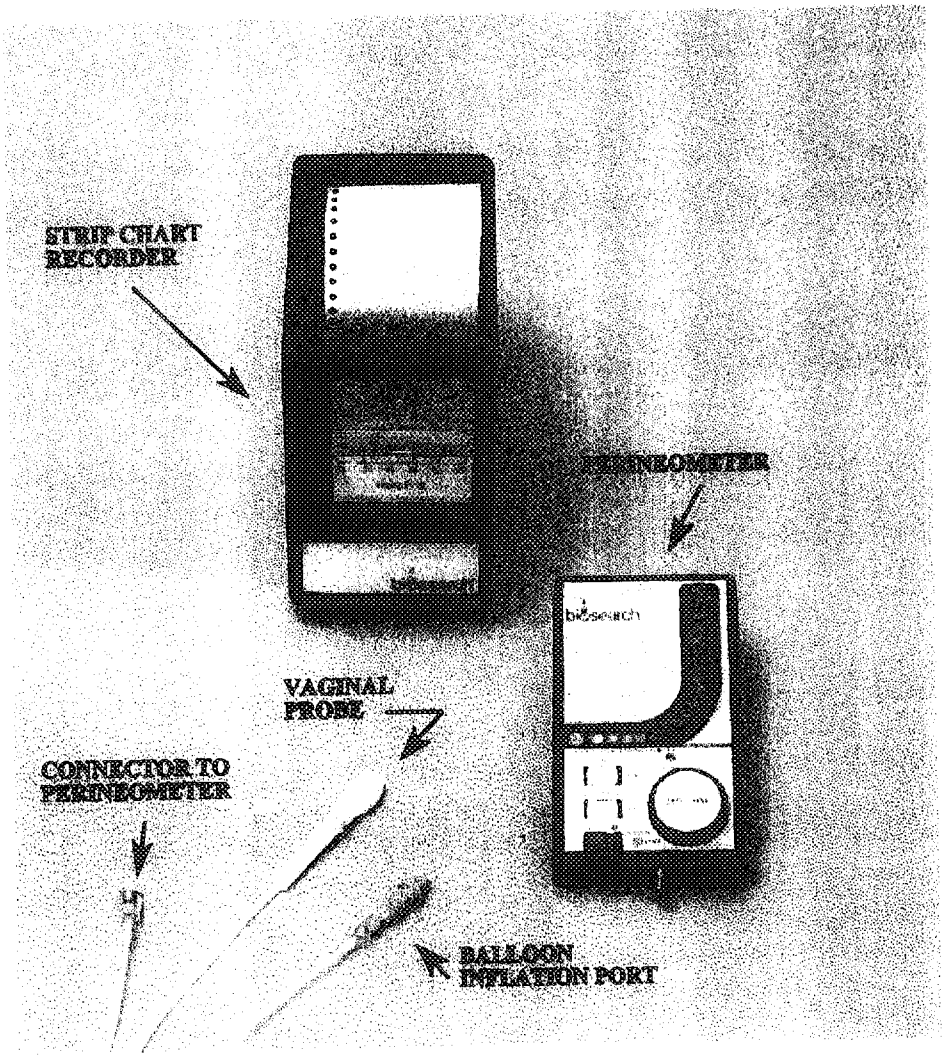
PERINEOMETER & VAGINAL PROBE

Why do pelvic muscle exercises (Kegal exercise): Without the strength and support of the pelvic floor muscles, urinary continence is difficult to maintain. Female urinary incontinence is usually associated with anatomical, neurological pelvic floor dysfunction. Presently many Urologist/Gynecologists are recommending pelvic muscle exercises to their female patients since these exercises will serve to enhance the strength and pelvic muscle control for the patient and in many cases improve urinary continence.

What need does this device address: The Perineometer (Biofeedback Monitor) and Vaginal Probe makes it possible for the patient to visualize their pelvic muscle activity. This is otherwise extremely difficult for the patient to monitor, due to the anatomical location of these muscles. This procedure must be performed at regular intervals as prescribed by the physician.



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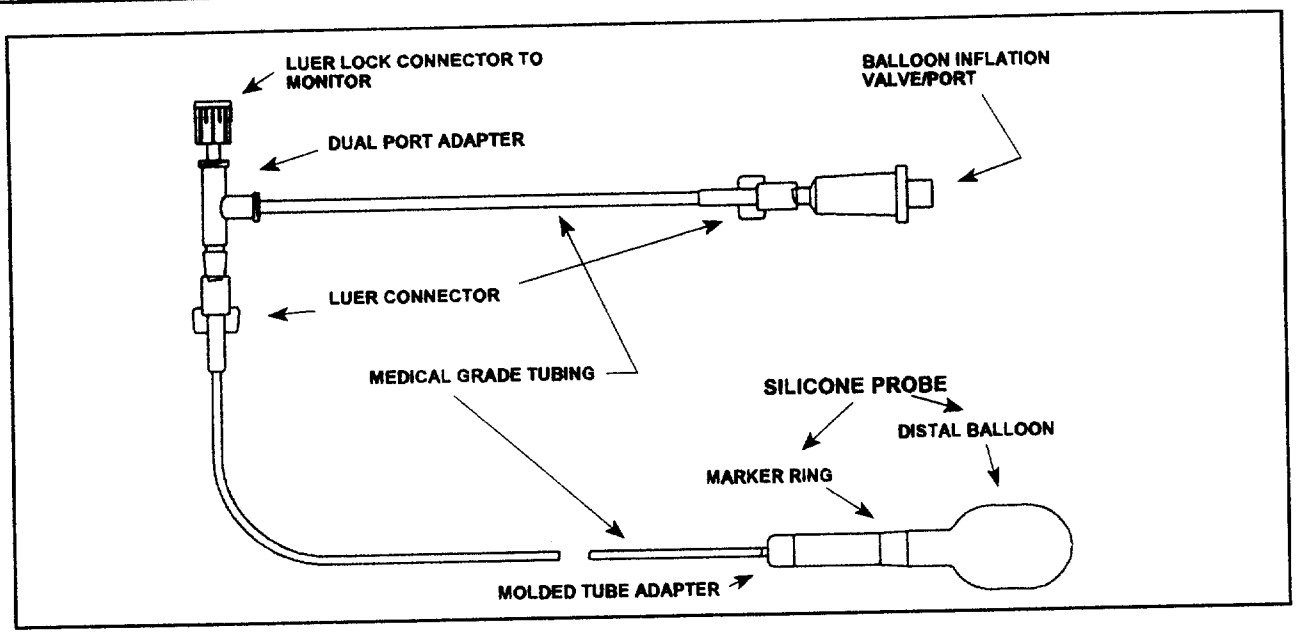
Biosearch Medical Products, Inc.
PERINEOMETER & VAGINAL PROBE

BIOCOMPATIBILITY DATA AND MATERIAL SPECIFICATIONS:



VAGINAL PROBE shown above is similar (except that the proximal balloon has been removed.) to the Anorectal probe which has been previously approved via the following Biosearch Medical Products 510(k)'s : k902843 (System #5 & Anorectal Probe) and k913736 (System #10 & Anorectal Probe).

*) **LUER LOCK CONNECTOR** -> (Not inserted into a body cavity) The material used is a Medical grade plastic.

*) **MEDICAL GRADE TUBING** -> (Not inserted into a body cavity) The material used is a Medical grade plastic.

*) **MOLDED TUBE ADAPTER** -> (Not inserted into a body cavity) The material used is a Medical grade plastic.

*) **SILICONE PROBE & SILICONE MARKER RING** -> The material used is USP class VI Silicone.

*) **LUER CONNECTOR & DUAL PORT ADAPTER** -> **(Not inserted into a body cavity)** The material used is a Medical grade plastic.

*) **BALLOON INFLATION VALVE/PORT** -> **(Not inserted into a body cavity)** The materials used are Medical grade plastics.

SAFETY & EFFECTIVENESS SUMMARY
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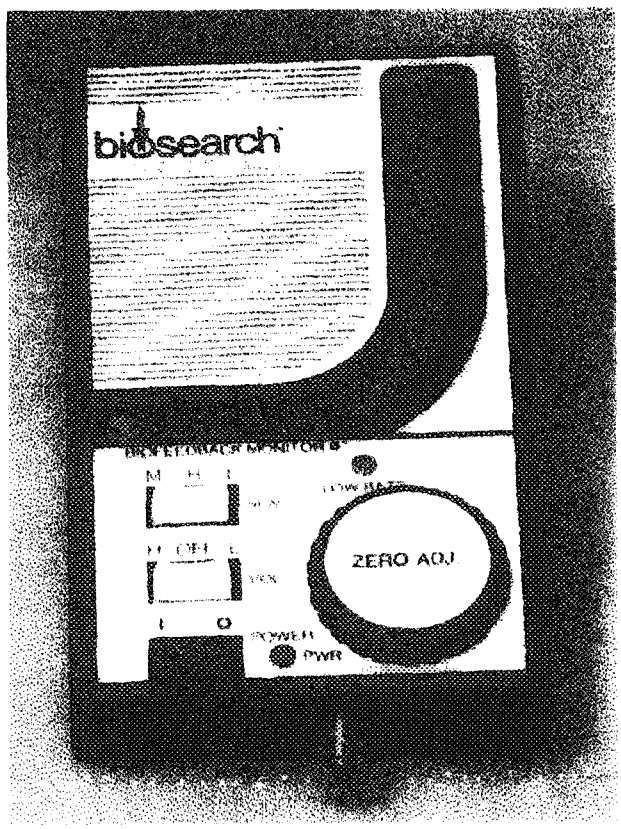
PERINEOMETER & VAGINAL PROBE

Cont. **BIOCOMPATIBILITY DATA AND MATERIAL SPECIFICATIONS:**

Perineometer



THIS IS A HAND HELD MONITOR. IT DOES NOT COME INTO CONTACT WITH MUCUS MEMBRANES OR BODY FLUIDS.

SPECIAL NOTE : PERINEOMETER has been previously approved via the following Biosearch Medical Products 510(k) : k902843 (System #5 & Anorectal Probe).

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PERINEOMETER & VAGINAL PROBE

MATERIAL	TEST DATE	TEST PERFORMED	RESULTS
Perineometer Model #20	NA	Device is identical to legally marked device known as Biosearch Biofeedback monitor #5	Previous 510(k) k902843
Anorectal Probe Assembly	11/11/91	Tested entire device for Cytotoxicity - MEM Elution	Nontoxic
Glue used to assemble the Anorectal probe	Vendor Provided	FDA Master File	Nontoxic
Silicone used in Anorectal Probe	Vendor Provided	USP tests for Class VI Plastics. (Hemolysis, Pyrogenicity, Intracutaneous Toxicity, Intramuscular implant for 90 days)	Meets the requirements of USP Class VI Plastic
Polyurethane Tubing Not inserted into patient.	Vendor Provided	USP tests for Class VI Plastics. (Cytotoxicity - Agarose overlay, Hemolysis, Intracutaneous Toxicity, Implantation Test)	Meets the requirements of USP Class VI Plastic
Luer Connectors Not inserted into patient.	Vendor Provided	USP tests for Class VI Plastics. (Acute Systemic toxicity , Intracutaneous Toxicity, Implantation Test)	Meets the requirements of USP Class VI Plastic
Molded Tube Adapter Not inserted into patient.	Vendor Provided	USP tests for Class VI. (Acute Systemic toxicity , Hemolysis-Direct & Extraction, Intracutaneous Toxicity, Muscle Implantation Test, Cytotoxicity - MEM Elution)	Meets the requirements of USP Class VI Plastic
Check Valve	Vendor Provided	ANSI/HIMA MD 70.1 British BS 5081,176	Meets the requirements

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PERINEOMETER & VAGINAL PROBE

EQUIVALENCE MATRIX (COMPARING USE AND TYPE)

NAME & 510(K) No.	PROBE (BALLOON TYPE)	PROBE (EMG TYPE)	USED FOR PELVIC EXERCISES	CAN BE INSERTED INTO THE VAGINA OR RECTUM (OPTIONAL)	USED FOR MALE BLADDER CONTROL	USED FOR FEMALE BLADDER CONTROL	PROBE INSERTED IN THE RECTUM	PROBE INSERTED IN THE VAGINA
BIOSEARCH "PERINOMETER & VAGINAL PROBE" {This Submission}	YES	NO	YES	YES	NO	YES	NO	YES
BIOSEARCH "ANORECTAL BIOFEEDBACK SYSTEM #5" {k902843}	YES	NO	YES	YES	NO	NO	YES	NO
BIOSEARCH "ANORECTAL BIOFEEDBACK SYSTEM #10" {k913736}	YES	NO	YES	YES	NO	NO	YES	NO
CARDIO DESIGN "PERITRON" {k945611}	YES	NO	YES	NO	YES	YES	YES	YES
MILEX "PERINEAL EXERCISER" {k862410}	YES	NO	YES	YES	NO	YES	NO	YES
HOLLISTER CONTIMED II" {k891774}	YES	NO	YES	YES	YES	YES	YES	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 1997

Mr. Martin Dyck
Vice President of Operations,
New Product Development Coordinator
Biosearch Medical Products, Inc.
P.O. Box 1700
Somerville, New Jersey 08876-1276

Re: K970145
PERINEOMETER & VAGINAL PROBE
(Biofeedback Monitor #20 and Vaginal Probe)
Dated: May 13, 1997
Received: May 15, 1997
Regulatory class: II
21 CFR §884.1425/Product code: 85 HIR

Dear Mr. Dyck:

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

510(k) Number (if known): K970145

Device Name: Perineometer & Vaginal Probe (Biofeedback Monitor #20 and Vaginal Probe)

Indications For Use:

INTENDED USE STATEMENT: The Perineometer (Biofeedback monitor) and vaginal probe are intended to be used to assist the patient in exercising her pelvic muscles (referred to Kegal exercises) which may lead to increased bladder control.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin M Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K97 0145

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)