UTAH MEDICAL PRODUCTS INC.

K970077

MAY 23 1997

510(k) Summary

January 3, 1997

Trade Name:	Liberty Plus System, PFS-300
Common Name:	Electrical Pelvic Floor Stimulation System With Biofeedback
Classifications:	Nonimplanted Electrical Continence Device. 21 CFR §876.5320 and Perineometer, 21 CFR §884.1425

The Utah Medical Products, Inc. (UMP) Liberty Plus System (PFS-300) is substantially equivalent to a combination of the UMP Liberty PFS System (PFS-200), cleared for marketing under K960496, with the Cardio Design Pty Ltd PFX Pelvic Floor Exerciser, cleared for marketing under K945611.

The device consists of a hand held electrostimulation unit and an injection molded thermoplastic applicator that supports two stainless steel electrode rings that apply electrical stimulation to a patient in order to help train neuromuscular tissue in the pelvic floor for improvement or restoration of urinary continence for women. The applicator includes a pressure transducer that provides biofeedback relating to the contractions of the pelvic floor muscles. The electrical stimulation energy and the power for the transducer are conducted to the electrodes via a six conductor cable and connector that plugs into the PFS-300. The transducer output signal is conducted back to an LCD graphical display by the same cable.

The PFS-300 is indicated for use to help train the pelvic floor muscles using electrical stimulation and biofeedback. The PFS-044 is a vaginal applicator that is used with the PFS-300. The PFS-300 is a battery powered electrostimulation device that applies electrical stimulation through electrodes on the PFS-044 applicator.

The technological characteristics of the UMP PFS-300 are substantially equivalent to the UMP PFS-200 since the stimulation output is identical. The PFS-300 has an LCD display that displays the oscillographic output from the pressure transducer in the PFS-044 applicator. The PFS-044 probe is substantially equivalent to the PFS-042 probe used with the PFS-200. They are the same size and shape and are manufactured from the same materials. The only difference is the pressure transducer that is enclosed in the PFS-044 that provides biofeedback to the user. The new device and the predicate device are both manufactured using biocompatible materials.

Laboratory tests of the PFS-300 and the PFS-200 have demonstrated that they provide equivalent electrical stimulation of the pelvic floor muscles. The PFS-300 and the Cardio Design Pty Ltd, PFX both display readings of the pressures generated by contractions of the pelvic floor muscles.

Kevin L. Cornwell
President & CEO

UTAH MEDICAL PRODUCTS, INC • 7043 South 300 West • Midvale, Utah 84047-1048 • 801/566-1200 • FAX#801/566-2062

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 1997

Mr. Kevin L. Cornwell
President & CEO
Utah Medical Products, Inc.
7043 South 300 West
Midvale, Utah 84047-1048

Re: K970077
Liberty Plus
Dated: January 7, 1997
Received: January 9, 1997
Regulatory class: II
21 CFR §876.5320/Product code: 78 KPI
21 CFR §884.1425/Product code: 85 HIR

Dear Mr. Cornwell:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4616. 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) K970077

Device Name: Liberty Plus System (PFS-300)

Indications For Use:

This device is intended as therapeutic aid in the conservative treatment of stress incontinence, urge incontinence or mixed stress and urge incontinence in women. Patients appropriate for this therapy should be selected using the following criteria:

Indications:

- Good general health, both mentally and physically.
- Urge incontinence due to detrusor instability or of idiopathic origin.
- Stress incontinence not associated with intrinsic sphincter deficiency.
- Mixed incontinence.
- Ability of patient to understand and demonstrate understanding of the use of the Liberty Plus System.
- Willingness to comply with the therapy plan.

Contraindications:

- Use of a cardiac pacemaker, or a history of rate or conductive disturbances.
- Neurological deficiency that would not permit proper sensory perception or stimulation.
- Currently pregnant or attempting to get pregnant.
- Anatomical vaginal structure that does not permit proper and complete placement of the vaginal probe.
- Irregular menstrual bleeding cycles.
- Any urinary or vaginal infections, localized lesions or other undiagnosed symptoms.
- History of urinary retention or current symptoms.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970077

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

(Optional Format 1-2-96)