Appendix Six

K983052

OCT 19 1998

Safety and Effectiveness Summary

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Background:
The Peritron Perineometer comprises a vaginal or anal Sensor, Readout Unit and interconnecting tube.

Perineometers are used in the diagnosis and treatment of stress incontinence in patients and for providing exercise feedback.
In the clinic Peritron is used to assess the condition of the pelvic floor muscles, (strength of contraction), teach pelvic floor exercises with the view to improving muscle strength and may be used at home as a biofeedback unit by patients performing pelvic floor exercises.

In operation, air displaced from the sensor caused by a voluntary contraction of the muscles of the pelvic floor travel to the readout units via the interconnecting tube. Peritron does not cause the contraction. These muscles are under the voluntary control of the user at all times.

1 Safety

None of these products diminish the safety level set by the substantially equivalent Contimed II™ (Hollister, Illinois) of Appendix 4(a) due to the following

1.1 Sensors

The key element concerning patient/user safety and the only contact component is the sensor.

As a principal manufacturer of catheters and tubing packs for Cardiac Surgery (Registered in Australia under the Therapeutic Goods Act as a GMP manufacturer but with no goods registered or offered for sale in the USA) we believe we have a good understanding of appropriate materials and manufacturing procedures necessary to produce a product of the highest biocompatibility and patient safety.

Accordingly we designed the sheath of the sensor (the only patient-contact surface) to be moulded in one piece without joins or crevices to potentially harbour bacteria. (In this respect it is safer than the vaginal sensor of the substantially equivalent Contimed unit, the several elements of which join together on the patient contact surface.) The sheath is injection moulded from liquid silicon rubber, Wacker Elastosil cat LR 3003/50A and LR/50B, that meets the requirements of FDA regulation 177.2600. Refer to documents in appendix 6(a)

As the sheath of the sensor contains 600ppm of blue pigment (Wacker cat RAL 5010 ref enclosure 6(c)) of unknown biocompatibility the FDA previously advised that we should conduct testing of the finished product. Refer to appendix 6 (a) for the test results.

1.2 Readout Unit

Peritron incorporates a pressure transducer and microprocessor to interpret the air pressure in the sensor and display it either numerically in cm water column pressure or as an analogue bar graph.

Hand-held Peritron weighs 220 gm and is powered by a standard 9 volt battery housed in an integral, user-accessible compartment separated physically from the electronic components.

All operating functions are controlled by one push-button.

The case of Peritron is of injection moulded plastic. There are no external parts that are of metal or are sharp and no electronic parts are accessible without the use of a tool.

At the time of the previous 510(k) application we understand electrical testing of the device was not required. However, since the previous approval we have had Peritron tested for Emission and Safety. The testing shows that Peritron is safe for the intended use. Refer to appendix 6(b) for test results.

1.3 Summary of Safety Features of Peritron

* Peritron is a passive device - it measures the result of a voluntary action of the user.
* There are no external wires, electrodes or electrical items of any kind.
* Internal user adjustments are neither required nor possible.
* A PVC tube is the only connection between the vaginal probe of the patient/user and the Readout unit.
* There are no liquids or dangerous items incorporated.
* All tests show that Peritron is safe for the intended use and meets standards where they exist.

Safety Experience

Since its inception in 1991, over 1200 units have been put into operation and at no time during the development or usage of the Peritron has there been an incident that in any way threatened the safety of any individual.

2. Effectiveness

Peritron does not alter the effectiveness compared to substantially equivalent Contimed II™ device as both devices measure the increase in air pressure in a sensor caused by a voluntary contraction of pelvic floor muscles.

Like Peritron, Contimed 11 conveys air from its sensor to the readout unit by means of a plastic tube.

Peritron is tested during manufacture for compliance with the performance criteria set out in the Brochure and Handbook of Appendix five. We would be pleased to make test results available on request.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 1998

Mr. Neville Motley
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P.O. Box 5407 BHBC
Baulkham Hills NSW 2153
AUSTRALIA

Re: K983052
Peritron, Model 9300A with Anal Sensor
Model 9300V with Vaginal Sensor
Dated: August 12, 1998
Received: September 1, 1998
Regulatory Class: II
21CFR 884.1425/Procode: 85 HIR

Dear Mr. Motley:

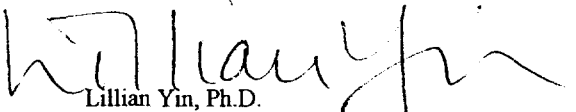
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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,



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): K983052

Device Name: PERITRON PERINEOMETER- Model 9300V or 9300A

Indications For Use:

Peritron is used in assessing the strength of pelvic floor muscles, teaching pelvic floor muscle exercises and for providing feedback during pelvic floor muscles exercises.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983052

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

(Optional Format 1-2-96)