DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1998

Robert E. Walter
President
Airtronic Services, Inc.
116 North Lively Blvd.
Elk Grove Village, IL 60007

Re: K974775
Single Channel Urological Pressure Gauge
Dated: October 31, 1997
Received: December 22, 1997
Regulatory Class: II
21 CFR 876.1620/Procode: 78 FAP

Dear Mr. Walter:

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): K974775

Device Name: Sinngle Channel Urological Pressure Guage,

Indications For Use:

The pressure sensor is for use in the long term weekly monitoring of full serial bladder (vesical) pressure in patients that perform regular clean intermittent catheterizations (CIC). Regular once per week long term monitoring of bladder pressure in patients at risk for developing high bladder pressures and urinary incontinence associated with, urinary tract infections (UTI), vesicoureteral reflux and renal insufficiency. The most significant source of urologic morbidity and mortality in patients with spinal conditions where CIC is used is renal failure secondary to upper tract deterioration from high bladder pressures.

Cystometry (CMG) is an integral part in the urologic evaluation of patients prior to the use of this device. At no time is this device to be used in place of CMGs for diagnostics. Patients with CMG leak point pressures greater than 40 cm H_20 are at significant risk for upper tract deterioration. The frequency and timing of CMG urodynamic studies in patients with spinal injuries continues to be controversial, but use of this device may insure that full CMGs or other suitable diagnostics are performed on a timely basis by the patients attending physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P Gatling

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974775

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)