NOV 26 1997

XIII . 510(k) Summary

K973268

Date: August 27, 1997

Submitted by: MicroAire® Surgical Instruments
1641 Edlich Drive
Charlottesville, VA 22911

Contact Person: Carl Angles
Director of Quality and Regulatory Affairs

Telephone: (804) 975-8000
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Proprietary Name: MicroAire® "Power Aspiration Device" *PAD*™ System
Common Name: Surgical Aspiration System
Classification Name: Surgical instrument motors and accessories/attachments, 21CFR §878.4820; Manual surgical instrument for general use, 21 CFR §878.4800

MicroAire believes the *PAD*™ System to be substantially equivalent in basic form and function to the following legally marketed devices:

- K832520 Wells Johnson Suction Tips
- K861878 Byron Suction Tips

The predicate devices are cannulae that are capable of being attached to a suction source. These devices are indicated for general aspiration of fluid or loose tissue. Both devices are essentially a closed, hollow steel tube with one or more openings at the tip. The cannulae are available in different lengths, diameter sizes, and tip configurations. They are connected to a suction source to create a negative pressure within the cannula. This negative pressure causes fluid and friable tissue to be suctioned into the cannula when it is inserted surgically. The surgeon is able to remove undesirable fluid and tissue accumulation by manually guiding the cannula through the treatment area.

The MicroAire® *PAD*™ System differs from the predicate devices in that it possesses a powered reciprocating cannula. The small (2-6 mm), rapid stroke of the *PAD*™ cannula simulates the manual hand motion that the surgeon would use during aspiration with the predicate devices. Thus, use of the *PAD*™ System does not raise safety and effectiveness issues that are significantly different from those of the predicate devices. At the same time, the powered cannula minimizes surgeon effort by

reducing the amount of necessary arm motion. Furthermore, the slight reciprocating action of the ***PAD***™ System facilitates the passage of the cannula through tissue. When the reciprocating action is not activated by the surgeon, the ***PAD***™ device functions in an identical manner to the predicate devices.

Laboratory tests showed that the ***PAD***™ System was comparable to predicate devices for the purpose of aspiration. Physiological saline and a viscous wound cleansing solution were aspirated by the ***PAD***™ System and a standard suction cannula. The wound cleansing solution had a consistency similar to synovial fluid or mucus. The fluids were aspirated by a vacuum pressure of 20 cm Hg for ten seconds. The volume of aspirated fluid was measured several times for both tools. There were no significant differences between the aspiration rates of the ***PAD***™ System and the regular suction cannula. The reciprocating cannula did not affect the rate of aspiration.

Nonclinical evaluations of the ***PAD***™ device also demonstrated its advantage over the predicate devices. The force required to enter soft tissue with reciprocating and nonreciprocating cannulae was quantified using *in vitro* animal experiments. The results of these tests demonstrated that the reciprocating cannula reduced the magnitude of penetration force by approximately 70%.

To ensure the safety of the MicroAire® ***PAD***™ System, the instruments comply with applicable standards. Sterility of the multiple-use ***PAD***™ instruments and power supply hoses can be achieved through the procedures detailed in AAMI's Good Hospital Practice-Steam Sterilization and Sterility Assurance. The disposable suction cannulae and tubing are pre-sterilized according to ANSI/AAMI/ISO 11137-1994, Sterilization of Health Care Products-Requirements for Validation and Routine Control-Radiation Sterilization. The MicroAire® 6025 electric console is designed to meet the electrical safety requirements of UL-544 and IEC-601-1. In addition, the components of the MicroAire® ***PAD***™ System are all comprised of materials with a long history of safety when incorporated in medical devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Carl Angles
Director of Quality and Regulatory Affairs
MicroAire Surgical Instruments, Incorporated
1641 Edlich Drive
Charlottesville, Virginia 22911

NOV 26 1997

Re: K973268
Trade Name: MicroAire ® "Power Aspiration Device" Pad™ System
Regulatory Class: II
Product Code: BTA
Dated: August 28, 1997
Received: August 29, 1997

Dear Mr. Angles:

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) 594-4595. 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973268

Device Name: MicroAire "Power Aspiration Device" PAD System

Indications For Use:

The MicroAire PAD System is indicated for the removal of tissue or fluid from the body during general surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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