Microaire Surgical Instruments, Inc.
Carl Angles
Director Of Quality And Regulatory Affairs
1641 Edlich Dr.
Charlottesville, Virginia 22911

June 8, 2021

Re: K981922
Trade/Device Name: Light Duty Pneumatic Instrument Model Number Pad-100, Heavy Duty Pneumatic Instrument Model Pad-200, Light Duty Electri
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Carl Angles:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 10, 1998. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 1998

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

Re: K981922
Trade Name: MicroAire® Power Aspiration Device, PAD™ System
Regulatory Class: II
Product Code: MUU
Dated: September 9, 1998
Received: September 10, 1998

Dear Mr. Angles:

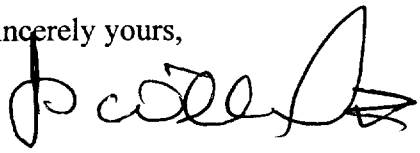
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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) 594-4595. 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): K981922

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 including suction lipoplasty for the purpose of aesthetic body contouring.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981922

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

(Optional Format 1-2-96)

XIV . 510(k) Summary

Date:	May 29, 1998
Submitted by:	MicroAire® Surgical Instruments 1641 Edlich Drive Charlottesville, VA 22911
Contact Person:	Carl Angles Director of Quality and Regulatory Affairs
Telephone: Fax:	(804) 975-8000 (804) 975-4123
Proprietary Name: Common Name: Classification Name:	MicroAire® "Power Aspiration Device" *PAD*™ System Surgical Aspiration System Suction lipoplasty system, 21CFR §878.5040.

The MicroAire® *PAD*™ System does not have a substantially equivalent predicate device that is legally marketed for the intended purpose of suction lipoplasty. The MicroAire® *PAD*™ System complies with appropriate voluntary standards designated as special controls to assure safety and effectiveness of the device in accordance with the requirements of 21 CFR §878.5040.

The MicroAire® *PAD*™ System consists of two primary components: a pneumatic or electric reciprocating handpiece and a disposable cannula with attached suction tubing. The disposable cannula with attached suction tubing connects to an external suction sources that is not part of the *PAD*™ System. A disposable cannula with attached tubing is also available with a syringe to facilitate manual suction. Performance specifications for these devices can be found in Appendix D.

The pneumatic reciprocating handpieces (Appendix E.1, E.4) operate with an air or nitrogen power supply. The handpieces are capable of driving the cannula through a stroke distance of 2.4-6mm (0.093-0.240in.) at a rate of 3500-4500 strokes per minute. The electric reciprocating handpiece (Appendix E.3) is capable of driving a cannula through a stroke distance of 2.4mm (0.093in.) at a rate of 3500-4500 strokes per minute. The electric handpiece is powered and controlled by the MicroAire® *Smartdrive*™ electric console (Appendix E.7).

The cannula is essentially a blunt tipped hollow tube comprised of stainless steel with an attached PVC suction tube and optional syringe (Appendix E.5, E.6). The cannula

internal diameter is approximately 3mm and ranges from 26-33cm in overall length. Fluid and tissue is aspirated through windows located near the tip of the cannula when the tubing is connected to a suction source. The number of windows varies between 3-6 openings with window lengths from 7-10mm at 2mm in width.

The small (2-6 mm), rapid stroke of the ***PAD***™ cannula simulates the manual hand motion that a surgeon would use during aspiration. 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 as a manual aspiration device.

Nonclinical evaluations also demonstrate that the ***PAD***™ reciprocating cannula reduces the force required to enter soft tissue. Comparison of reciprocating and nonreciprocating cannulae was accomplished by alternating the ***PAD***™ instrument between the "on" and "off" positions during successive trials of *in vitro* animal experiments. The results of these tests demonstrated that the reciprocating cannula reduced the magnitude of penetration force by approximately 70% (Appendix F).

Laboratory tests demonstrated the ***PAD***™ Systems ability to perform aspiration. Physiological saline and a viscous wound cleansing solution were aspirated. 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 and the volume of aspirated fluid was measured (Appendix F). The reciprocating cannula did not affect the rate of aspiration.

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. A steam validation study was conducted on the handpiece with the following results: Gravity Discharge (wrapped or unwrapped) - 35 minutes @ 270°F (132°C) and 8 minute drying cycle. Prevacuum System - 4 minutes @ 270°F (132°C) and 8 minute drying cycle. The disposable suction cannulae and tubing are pre-sterilized at 25-40 kiloGray 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.