MICROAIRE SURGICAL INSTRUMENTS, LLC **February 9, 2023**
Attention: Glenn Gerstenfeld
3590 Grand Forks Blvd.
Charlottesville, VA 22911

Re: BK220705 (Formally K150779)
Trade/Device Name: LipoFilter - Hospital Pack LipoFilter - Clinic Pack
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Mr. Gerstenfeld:

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 May 22, 20215. Specifically, FDA is updating this SE Letter because FDA has assigned your submission a new submission tracking number and created a new product code to better categorize your device technology.

Please update the registration and listing of the device within the FURLS Device Registration and Listing Module according to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm

For more information, please refer to the Federal Register Notice *Consolidation of Devices That Process Autologous Human Cells, Tissues, and Cellular and Tissue-Based Products at the Point of Care To Produce a Therapeutic Article* (86 FR 50887, available at https://www.federalregister.gov/documents/2021/09/13/2021-18912/consolidation-of-devices-that-process-autologous-human-cells-tissues-and-cellular-and-tissue-based).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact the Regulatory Project Manager, Julia Russell at 240-704-0618 or by email at Julia.Russell@fda.hhs.gov.

Sincerely,

Wilson W. Bryan, MD
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center WO66-G609
Silver Spring, MD 20993-0002

May 22, 2015

MicroAire Surgical Instruments LLC
Mr. Chris Spofford
Regulatory Affairs and Compliance Officer
3590 Grand Forks Boulevard
Charlottesville, Virginia 22911

Re: K150779
Trade/Device Name: Microaire LipoFilter System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: March 25, 2015
Received: March 26, 2015

Dear Mr. Spofford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150779

Device Name
Microaire LipoFilter System

Indications for Use *(Describe)*
The MicroAire LipoFilter System is used in the aspiration, harvesting, filtering and transferring of autologous adipose tissue for aesthetic body contouring. If the harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1) Preparation Date: March 24, 2015

2) Submitted by:
MicroAire Surgical Instruments LLC
3590 Grand Forks Boulevard
Charlottesville, Virginia 22911
Owner/Operator #: 9004658

3) Contact Person/Prepared by:
Chris Spofford
Regulatory Affairs and Compliance Officer
MicroAire Surgical Instruments
(434) 975-8344
Chriss@microaire.com
3590 Grand Forks Boulevard
Charlottesville, Virginia 22911

4) Device Identification:

Trade Name: MicroAire LipoFilter System
Common Name: Lipoplasty Suction System
Classification: Suction lipoplasty system (21 CFR 878.5040, Product Code MUU)

5) Predicate Device:
Sound Surgical Technologies – Origins LipoHarvesting System (K120328)
Medical Device Resource Corporation – Lipisystems Aquavage Model AV2000 & 1200 (K092284)

6) Device Description: The MicroAire LipoFilter System consists of a single use, closed loop tissue collection system comprised of a medical grade canister, vacuum port, collection port, tissue port and lid intended to be used with a standard liposuction aspiration system pump to collect fatty tissue for aesthetic body contouring. As the tissue is harvested from the patient, it enters the canister via the collection port in the canister lid. The physician removes unwanted waste materials from the collection system via the vacuum port by closing a valve. This process leaves fatty tissue that can be transferred to syringes via the tissue port for autologous fat re-injection.

7) Intended Use: The MicroAire LipoFilter System is used in the aspiration, harvesting, filtering and transferring of autologous adipose tissue for aesthetic body contouring. If the harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

8) Comparison to Predicate:

Table 1: Substantial Equivalence Comparison Chart

FEATURES	DEVICES		
	MicroAire LipoFilter System	**Origins LipoHarvesting System**	**Medical Device Resource Corp Lipisystems Aquavage**
Device Description:	The MicroAire LipoFilter System consists of a single use, closed loop tissue collection system comprised of a medical grade canister, vacuum port, collection port, tissue port and lid intended to be used with a standard liposuction aspiration system pump to collect fatty tissue for aesthetic body contouring. As the tissue is harvested from the patient, it enters the canister via the collection port in the canister lid. The physician removes unwanted waste materials from the collection system via the vacuum port by closing a valve. This process leaves fatty tissue that can be transferred to syringes via the tissue port for autologous fat re-injection.	The Origins LipoHarvesting System consists of a reusable, closed loop tissue collection system comprised of a medical grade canister, a drain port and a lid intended to be used with a standard liposuction aspiration pump to collect fatty tissue for aesthetic body contouring. As the tissue is harvested from the patient, it enters the collection canister via a port in the canister lid. The physician removes unwanted waste materials from the collection system via the drain port at the base. This process leaves fatty tissue that can be transferred to syringes for autologous fat re-injection.	Device function: 1. Contains port interfaces between: canister to tubing and aspirator to canister. 2. Sterile tubing to connect the interfaces. 3. Funnel to interface port to tubing. 4. Syringe to collect fat. Device Design: 1. Contents subjected to sterility. Material used: Plastic canister, syringe, silicone tubing.
Picture of Product			

Intended Use:	The MicroAire LipoFilter System is used in the aspiration, harvesting, filtering and transferring of autologous adipose tissue for aesthetic body contouring. If the harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.	The Origins LipoHarvesting System is used in the aspiration, harvesting, filtering and transferring of autologous tissue. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.	For use in aspirating subcutaneous fatty tissue including autologous fat collection.
Technology Comparison:	The MicroAire LipoFilter System employs the same technological characteristics as the predicate device.	The Origins LipoHarvesting System employs the same technological characteristics as the predicate devices.	The Lipisytems Aquavage employs the same technological characteristics as the predicate device.
Suction Source(s)	Aspiration device	Aspiration device	Aspiration device
Volume Range	Up to 2500mL	100 to 2,000 mL	2000cc or 1200cc
Shipped sterile	Yes	No, sterilized by user prior to use	Yes
Initial method	Gamma radiation	Not applicable	Gamma radiation
Sterility assurance level	10^{-6}	10^{-6}	10^{-6}
Disposable or reusable	Single use, disposable	Reusable	Single use, disposable
Resterilization method	Not applicable	Autoclave	Not applicable

9) Pre-Clinical Testing

The MicroAire LipoFilter System has been tested in various ways to demonstrate equivalence to the predicate devices including Gamma Radiation validation, shelf life validation, biocompatibility, and various performance testing. Specifics include the following:

Validated for sterility using gamma radiation. Test results and analyses indicate that the MicroAire LipoFilter System sterility complies in accordance with ISO 11137-1:2006 and ISO 11137-2:2006.

Validated for a 2 year shelf life. Test results and analyses indicate that the MicroAire LipoFilter System packaging complies in accordance with ISO 11607-1: 2006 and ISO 11607-2: 2006.

The MicroAire LipoFilter System has patient contact materials and is made from medical grade biocompatible materials. Test results and analyses indicate that the MicroAire LipoFilter System materials' complies in accordance with ISO 10993-1: 2009.

The MicroAire LipoFilter System was tested for performance in accordance with its predetermined specifications on file at MicroAire which includes functionality testing, ISO 10079-1 testing, tubing connection strength testing, vacuum leak testing, adipocyte viability testing, and Aging Studies.

10) Conclusion:

The MicroAire LipoFilter System uses decantation to separate the tissue which is the same method as the two identified predicate devices. The MicroAire LipoFilter System does not have any new intended uses as compared to the two predicate devices. The MicroAire LipoFilter System has a slightly larger volume (2500 mL) whereas the predicate devices have a volume of up to 2000 mL which is insignificant given the intended use of the devices. The MicroAire LipoFilter System is provided sterile whereas the predicate devices are either provided sterile and/or sterilized by the user. The results of these activities demonstrate that the MicroAire LipoFilter System is considered substantially equivalent to the two predicate devices.

The results of the evaluation above demonstrate that the MicroAire LipoFilter System is considered substantially equivalent to the two predicate devices.