510(k) Summary

MicroAire LipoFilter® System

BK220674

1. Submission Sponsor

MicroAire Surgical Instruments, LLC.
3590 Grand Forks Boulevard
Charlottesville, Virginia 22911
USA
Glenn Gerstenfeld
Vice President, QA/RA, and Compliance Officer
Glenn.gerstenfeld@microaire.com
Phone: (434) 975-8344
Fax: (434) 975-4144

2. Submission Correspondent

Glenn Gerstenfeld
Vice President, QA/RA, and Compliance Officer
Glenn.gerstenfeld@microaire.com
Phone: (434) 975-8344

3. Date Prepared

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4. Device Identification

Trade/Proprietary Name:	MicroAire LipoFilter® System
Common/Usual Name:	Lipoplasty Suction System
Classification Name:	System, Suction, Lipoplasty
Regulation Number:	21 CFE 878.5040
Product Code:	MUU
Class:	Class II
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

MicroAire Surgical Instruments LLC – MicroAire LipoFilter® System (K150779)

6. Indication for Use Statement

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.

7. Device Description

The MicroAire LipoFilter® Clinical Pack 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. The process leaves fatty tissue that can be transferred to syringes via the tissue port for autologous fat re-injection.

8. Substantial Equivalence Discussion

The following table compares the MicroAire LipoFilter® System to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Comparison of Characteristics

Attribute	MicroAire LipoFilter® System (Subject Device)	MicroAire LipoFilter® System (Predicate Device)	Difference
General Information			
510(k) Number	BK220674	K150779	N/A
Product Code	MUU	MUU	Same – no difference
Product CFR	880.5040	880.5040	Same – no difference
Product Class	2	2	Same – no difference

Attribute	MicroAire LipoFilter® System (Subject Device)	MicroAire LipoFilter® System (Predicate Device)	Difference
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 reinjection.	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 reinjection.	Same – no difference
Product Picture			Same – no difference
Indications for 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 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.	Same – no difference
Intended Use	Single-use collection canister used in the harvesting and transferring of autologous adipose tissue.	Single-use collection canister used in the harvesting and transferring of autologous adipose tissue.	Same – no difference

Attribute	MicroAire LipoFilter® System (Subject Device)	MicroAire LipoFilter® System (Predicate Device)	Difference
Technology Comparison			
Volume Range	Up to 2500 mL	Up to 2500 mL	Same – no difference
Shipped Sterile	Yes	Yes	Same – no difference
Suction source(s)	Aspiration device	Aspiration device	Same – no difference
Sterilization Method	Gamma Radiation	Gamma Radiation	Same – no difference
Disposable or Reusable	Single use, disposable	Single Use, disposable	Same – no difference
Re-sterilization Method	N/A – single use for Clinical Pack	N/A – single use for Clinical Pack	Same – no difference
Shelf-life (Clinical Pack)	1 year	1 year	Same – no difference
Materials used	• The components that come into contact with the patient tissue are constructed of polycarbonate, polyethylene, polypropylene, and silicone. • Outer Lid: Polycarbonate w/ blue colorant • Canister Lid: Polycarbonate w/ blue colorant	• The components that come into contact with the patient tissue are constructed of polycarbonate, polyethylene, polypropylene, and silicone. • Outer Lid: Polycarbonate w/ blue colorant • Canister Lid: Polycarbonate w/ blue colorant	Same – no difference
Packaging Comparison			
Primary Packaging	• Rigid thermoformed tray • Tyvek lid	Flexible film (Nylon) pouch	Difference – subject device in a sturdier enclosure
Secondary Packaging	200# E Fluted carton 14.38″x11.63″x7.75″	200# E Fluted carton 16″x16″x8″	Difference – subject device in a smaller carton

Attribute	MicroAire LipoFilter® System (Subject Device)	MicroAire LipoFilter® System (Predicate Device)	Difference
Secondary Packaging Dunnage	None	Polyurethan foam inserts - Top - Bottom - 3 of 4 sides	Difference – subject device has no dunnage
Labeling	• Primary label contains symbol for sterile barrier. • Secondary label contains symbol for protective layer • Instruction for use compliant to EU MDR requirements • Instruction for opening rigid primary package.	• Two identical labels – one applied to the primary packaging, the other to the secondary packaging. • Instruction for use compliant to EU MDD requirements • Instruction for opening flexible primary package.	Difference – subject device label identification and instructions amended to align with changes in requirements and packaging

9. Non-Clinical Performance Data

There were no changes in the design, technological features, or intended use associated with the MicroAire LipoFilter® System (sterile Clinical Pack only). The change was to the packaging where sterilization, usability, and packaging of the MicroAire LipoFilter® Clinical Pack was validated through a series of FDA-recognized standards.

The change in packaging did not affect the performance tests of the device conducted in K150779 and these tests are applicable and valid to the subject device of this submission. The testing included:

- Functionality testing,
- ISO 10079-1 testing,
- Tubing connection strength testing,
- Vacuum leak testing,
- Adipose viability testing, and
- Aging studies

Biocompatibility was evaluated with a risk approach to ISO 10993-1. With changes in packaging, no patient contacting components are affected and thus conclude there is no new concerns and questions related to the safety of the device for biocompatibility.

10. Statement of Substantial Equivalence

The MicroAire LipoFilter® System uses decantation to separate the tissue which is the same method as the identified predicate device. The MicroAire LipoFilter® System does not have any new intended uses as compared to the predicate device. The MicroAire LipoFilter® System has the same safety and technological characteristics compared to the predicate device.

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