

510(k) Summary

Device Trade Name: LipoGrafter® Kit

Manufacturer: Musculoskeletal Transplant Foundation (MTF Biologics)
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Classifications: 21 CFR 878.5040; Suction lipoplasty system

Class: II

Product Codes: QKL

Primary Predicate: K172714 LipiVage® by Genesis Biosystems, Inc.

Indications For Use:

The LipoGrafter® Kit is indicated to facilitate Autologous Fat Transfer (AFT). AFT is the harvesting, sedimenting and transfer of autologous fat tissue back into the same patient following a medical procedure. The device is intended for use when the transfer of harvested adipose tissue is desired for aesthetic body contouring. The device is intended for use in the following surgical specialties: orthopedic surgery, arthroscopic surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and plastic and reconstructive surgery. Only legally marketed accessory items, such as syringes and cannulas, should be used with the system. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

Device Description:

The LipoGrafter Kit is a sterile, non-pyrogenic, single use disposable device that is used in harvesting, sedimenting, and transferring autologous fat to the desired anatomy. The components of the LipoGrafter Kit include: KVAC® Syringe, AT-Valve®, 4 Collection bags with silicone tubing and luer connectors. These devices utilize standard luer lock connections per ISO 80369-7 and are used in combination with FDA-cleared syringes and cannulas.

Comparison of Technological Characteristics:

	Subject Device LipoGrafter Kit by MTF Biologics	Predicate Device BK 220714 (K172714) LipiVage® by Genesis Biosystems, Inc.	Comparison
Administrative Information			
Common Name	Lipoplasty System	Lipoplasty System	Same
Regulation Number	21 CFR 878.5040	21 CFR 878.5040	Same
Device Class	Class II	Class II	Same
Product Code	QKL; Lipoaspirate Washing System for Aesthetic Body Contouring	MUU; Lipoplasty System, Suction	Same (with current product code)
Classification Panel	General and Plastic Surgery	General and Plastic Surgery	Same
Intended Use			
Indications for Use	The LipoGrafter® Kit is indicated to facilitate Autologous Fat Transfer (AFT). AFT is the harvesting, sedimenting and transfer of autologous fat tissue back into the same patient following a medical procedure. The device is intended for use when the transfer of harvested adipose tissue is desired for aesthetic body contouring. The device is intended for use in the following surgical specialties: orthopedic surgery, arthroscopic surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and plastic and reconstructive surgery. Only legally marketed accessory items, such as syringes and cannulas, should be used with the system. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.	LipiVage® is used for aspiration, harvesting, filtering, and transferring of autologous adipose tissue for aesthetic body contouring. The system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation. LipiVage® is intended for use in the following surgical specialties when aspiration of soft tissue is desired: plastic and reconstructive surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery.	Similar The only difference is in the predicate uses a legally marketed vacuum or aspirator apparatus as a source of suction. The subject system design includes a source of suction in the syringe.

Technological Characteristics			
System	Closed loop, kit with syringe	Closed loop, kit with syringe	Same
Use and Sterility	Single-use, sterile	Single-use, sterile	Same
Biocompatibility	Biocompatible	Biocompatible	Same
Method of Separation	Collection (decantation) bag and gravity	Plunger with in-line filter in the syringe	Different

Source of Energy / Suction	Syringe with embedded constant force springs	Vacuum or aspirator apparatus at the user facility	Different
Centrifuge Required	No	No	Same
Compatible with legally marketed aspiration / injection cannulas and syringes	Yes	Yes	Same

Performance Testing Summary:

Non-clinical testing included:

- Adipocyte cell viability testing
- Usability evaluation
- Plunger force test
- Vacuum pressure assessment
- Biocompatibility evaluation
- Material-mediate pyrogenicity testing
- Bacterial endotoxin testing
- Sterilization validation
- Packaging validation

Substantial Equivalence:

The subject device and the predicate device have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are both provided sterile for single-patient use. The differences between the subject and predicate devices include the method of fat separation (decantation vs. in line filter) and the source of suction (syringe with constant force springs vs. legally marketed source of suction at the user facility). The data supplied in this submission demonstrates the ability of the subject design to perform the intended use.

Conclusion:

Based on the comparison of intended use and technological characteristics, MTF Biologics has demonstrated the subject LipoGrafter Kit is substantially equivalent to the predicate device.