510(k) Summary

I. SUBMITTER

Owner/Submitter:	Alma Lasers, Inc. 485 Half Day Rd Suite # 100 Buffalo Grove, Illinois, 60089
Phone:	224-377-2019
Contact Person:	Jessica Rivera-Montejo
Date Prepared:	May 5, 2023

II. DEVICE

Name of Device:	VorFat System
Common or Usual Name:	Lipoaspirate Washing System For Aesthetic Body Contouring
Classification Name:	Suction Lipoplasty System
Regulation Number:	21 CFR 878.5040
Regulatory Class:	Class II
Product Code:	QKL
Classification Panel:	General and Plastic Surgery

III. PREDICATE DEVICE

Primary:	The Lipogems System, K171135 / BK220712

IV. DEVICE DESCRIPTION

The canister with filter (fat canister) of the VorFat System is a closed loop tissue collection system that includes a vacuum port, collection port, tissue port and lid. The canister with filter was previously cleared in K092482. It is used with legally marketed lipoplasty systems to separate, filter, and microfragment adipose tissue for re-injection. As the tissue is harvested from the patient, it enters the collection canister via the collection port in the canister lid. The vacuum port is connected to the standard waste canister, which is connected between the device and the legally marketed lipoplasty system. During harvest, waste is filtered out to the waste canister. After harvest, the collection canister is secured in the adapter attached to the mixer. The mixer applies a mechanical action to the tissue in the collection canister that allows for reduction of the fat cluster sizes. This gentle processing diminishes tissue damage, thereby preserving the cell viability and tissue micro-architecture of the adipose tissue. The product is a micronized fraction of fatty tissue that can be transferred to syringes via the tissue port for autologous fat re-injection. The canister filter is offered in a 100mL size.

The subject device VorFat System includes a canister, vortex mixer with canister adapter, and sterile cover for the mixer. The mechanical action of the Subject Device mixer produces a micronized fraction of the adipose tissue, and this technological characteristic is comparable to the predicate device K171135/BK220712. There is no additional non-manual energy delivered to aid in fragmentation of the adipose tissue.

V. INDICATION FOR USE

The VorFat System is intended for the closed-loop processing of lipoaspirate tissue in medical procedures involving the harvesting, concentrating and transferring of autologous adipose tissue harvested with a legally marketed lipoplasty system. The device is intended for use in the following surgical specialties when the transfer of harvested adipose tissue for aesthetic body contouring is desired:

- orthopedic surgery,
- arthroscopic surgery,
- neurosurgery,
- gastrointestinal and affiliated organ surgery,
- urological surgery,
- general surgery,
- gynecological surgery,
- thoracic surgery,
- laparoscopic surgery,
- plastic and reconstructive surgery

Only legally marketed accessory items, such as syringes, should be used with the system. Any fat concentrated with this system is to be transferred back to the patient without any additional manipulation.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The VorFat System is substantially equivalent in terms of indications for use, technological characteristics, and performance characteristics to the predicate device. Tissue collection, separation and filtering for autologous reinjection is the technological principle for the predicate device. The VorFat System is substantially equivalent to the predicate device in terms of mechanical processing to produce a micronized fraction of tissue for autologous transfer using syringes.

The following Table provides a comparison and evidence of substantial equivalence of the subject device with the predicate device:

Characteristic	Primary Predicate K171135 / BK220712	Subject Device	Comparison
Device Name	The Lipogems System	VorFat System	N/A
Product Code	MUU / QKL	QKL	Same
Regulation	21 CFR 878.5040	21 CFR 878.5040	Same
Intended Use	Mechanical processing, filtering and transferring of autologous adipose tissue	Mechanical processing, filtering, and transferring of autologous adipose tissue	Same
Indications for Use	The Lipogems System is a sterile medical device intended for the closed-loop processing of lipoaspirate	The VorFat System is intended for the closed-loop processing of lipoaspirate tissue in medical	Same

Characteristic	Primary Predicate K171135 / BK220712	Subject Device	Comparison
	tissue in medical procedures involving the harvesting, concentrating and transferring of autologous adipose tissue harvested with a legally marketed lipoplasty system. The device is intended for use in the following surgical specialties when the transfer of harvested adipose tissue is desired: 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 when aesthetic body contouring is desired. Only legally marketed accessory items, such as syringes, should be used with the system. If harvested fat is to be transferred, the harvested fat is only to be used without any additional manipulation.	procedures involving the harvesting, concentrating and transferring of autologous adipose tissue harvested with a legally marketed lipoplasty system. The device is intended for use in the following surgical specialties when the transfer of harvested adipose tissue for aesthetic body contouring is desired: 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, should be used with the system. Any fat concentrated with this system is to be transferred back to the patient without any additional manipulation.	
Prescription Use	Yes	Yes	Same
Design Features	The fat canister filter works with an aspiration system to separate, mechanically process, and filter adipose tissue for autologous reinjection.	The fat canister filter works with an aspiration system to separate, mechanically process, and filter adipose tissue for autologous reinjection. The fat canister is provided in the manufacturer's original packaging with original labeling.	Same
Operational Principle	Fat is aspirated into a syringe, and transferred to the Lipogems System device, where under constant gravity the fat is mixed with saline and undergoes micronization of the lipidic clusters through a sieve. The unit is shaken while the saline flows through, thus removing oil and blood residuals, and further reducing the clusters. This processing diminishes tissue disaggregation, thus preserving the cell and tissue micro-architecture of the adipose tissue. Finally, the concentrated adipose tissue clusters are passed out of the device into a collecting syringe for transferring back to the patient.	The VorFat System is a closed loop tissue collection system that includes a canister filter (fat canister) and vortex mixer, used with a legally marketed lioplasty system to separate, filter, and microfragment adipose tissue for autologous reinjection. The canister is connected to a rapid stirrer/vortex mixer. The mechanical mixing action diminishes tissue disaggregation, thus preserving the cell and tissue micro-architecture of the adipose tissue. The result of processing with the VorFat System is a homogenous and micronized fraction of adipose tissue, which allows a patient's subcutaneous fat to be processed for autologous reinjection within the operative procedure time.	Substantially equivalent
Sterility	Canister: Sterile, SAL 10^{-6} Mixer: Shaken by hand by user	Canister: Sterile, SAL 10^{-6}, purchased from third party, previously cleared Mixer: Non-sterile (covered with sterile sleeve during use)	Same
Single Use?	Canister: Single Use	Canister: Single Use Mixer: Multi-use Cover sleeve: Single Use	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Bench Testing/Assessment
The following evaluations were performed for the VorFat System configuration to demonstrate substantial equivalence:

- Tissue Cluster Size Analysis (Adipose Aggregate/Cluster Size in mm^2)
- Cell Viability
- Red Blood Cell Content

Both the subject and predicate devices had suitable characteristics for their indication for use.

VIII. CONCLUSIONS

Based on the information contained within this submission, Alma Lasers, Inc. believes that the VorFat System is substantially equivalent to the identified predicate device and does not introduce any new or significantly modified risks, and no new questions of safety and efficacy.