DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 19, 2015

Ranfac Corporation
Mr. Christopher P. Whelan
Senior Vice President - Quality
30 Doherty Avenue
Avon, Massachusetts 02322

Re: K150156
Trade/Device Name: Ranfac Fat Aspiration Transfer Syringe (FATS) Procedure Pack
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: September 11, 2015
Received: September 14, 2015

Dear Mr. Whelan:

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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and

809]); 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)*
K150156

Device Name
Ranfac Fat Aspiration Transfer Syringe (FATS) Procedure Pack

Indications for Use *(Describe)*

The Ranfac FATS Procedure Pack is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. The FATS Procedure Pack is for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The device is intended for use in the following surgical specialties when the concentration of harvested adipose is desired: Neurosurgery, gastrointestinal surgery, urological surgery, plastic & reconstructive surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, arthroscopic surgery.

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.

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510(k) Summary (Page 1 of 4)

The contents of this 510(k) summary have been provided in conformance with 21 CFR §807.92 "Content and Format of a 510(k) Summary".

1. Submitter/Sponsor

Ranfac Corp.
30 Doherty Avenue
Avon MA 02322
FDA Registration Number 1211566
Telephone Number/Fax: 508-588-4400 ext. 106/508-584-8588
Contact Person: Christopher P. Whelan
Date Prepared: December 30, 2014

2. Device Name

Trade Name: Ranfac Fat Aspiration Transfer Syringe (FATS) Procedure Pack
Common or Usual Name: Fat Transfer Syringe Procedure Pack
Classification Name: Suction Lipoplasty System
21 CFR §878.5040, Procode MUU
Classification: Class II

3. Predicate Device:

Trade Name	510(k)	Company
Harvest AdiPrep System	K121005	Harvest Technologies

4. Device Description

The Ranfac Fat Aspirate Transfer System (FATS) is designed to allow for sterile processing and transfer of the collected adipose tissue. The device consists of a procedure pack including the following components: two sterile centrifugation syringes, two each 30 mL and 20 mL sterile syringes for adipose tissue aspirate transfer, and other luer fittings as accessories to be used to transfer into and from the centrifugation syringe. Additionally, a non-sterile, reusable centrifugation syringe Containment Vessel is provided as a separate accessory which allows the centrifugation syringe to fit within a commercially available centrifuge.

510(k) Summary (Page 2 of 4)

5. Indications For Use

The Ranfac FATS Procedure Pack is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. The FATS Procedure Pack is for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The device is intended for use in the following surgical specialties when the concentration of harvested adipose is desired: Neurosurgery, gastrointestinal surgery, urological surgery, plastic & reconstructive surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, arthroscopic surgery.

6. Comparison of the Technological Characteristics With the Predicate Devices:

As compared with the predicate device, and as shown below, the Ranfac FATS device has the same indications for use, and has similar technological and operational characteristics when compared with the predicate device.

Table 5.1 Comparison of the Proposed Ranfac FATS System to the Predicate Harvest AdiPrep Adipose Transfer System

	Ranfac FATS (This Submission)	**Harvest AdiPrep (K121005)**
Intended Use	The Ranfac FATS Procedure Pack is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. The FATS Procedure Pack is for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The device is intended for use in the following surgical specialties when the concentration of harvested adipose is desired: Neurosurgery, gastrointestinal surgery, urological surgery, plastic & reconstructive surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, arthroscopic surgery.	The AdiPrep Adipose Transfer System is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. The AdiPrep system is for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The AdiPrep Adipose Transfer System is intended for use in the following surgical specialties when the concentration of harvested adipose is desired: Neurosurgery, gastrointestinal surgery, urological surgery, plastic & reconstructive surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, arthroscopic surgery.
Components	Syringe with removable plunger, aspiration & fat injection syringes and accessory caps and luer fittings.	Syringe with removable plunger, aspiration & fat injection syringes, accessory caps and luer fittings, skin puncture needles, and oil extraction syringe & needle.

510(k) Summary (Page 3 of 4)

Table 5.1 Comparison of the Proposed Ranfac FATS System to the Predicate Harvest AdiPrep Adipose Transfer System

	Ranfac FATS (This Submission)	Harvest AdiPrep (K121005)
Centrifugation Syringe	Modified standard hypodermic syringe with a polypropylene barrel with printed graduations, and a plunger composed of a polypropylene body supporting an elastomer seal (i.e., plunger tip). The plunger is removed prior to centrifugation to allow the syringe to fit within the centrifuge. The FATS centrifugation syringe has a second gasket that serves as a barrier to help maintain vacuum pressure within the syringe during centrifugation and minimizes exposure of the syringe contents with air. The centrifugation syringe has a male luer-lock which is attached to a female-female luer lock to transfer the concentrated fat to an injection syringe.	Modified standard hypodermic syringe with a Cyclo Olefin Polymer (COP) barrel with printed graduations, and a plunger composed of a polypropylene or ABS body supporting a silicone seal (i.e., plunger tip). The plunger is removed prior to centrifugation to allow the syringe to fit within the centrifuge. The AdiPrep centrifugation syringe has a lipid barrier which provides isolation of oils and lipids from adipose tissue and minimizes exposure of the concentrated adipose tissue with air. The centrifugation syringe has a male luer-lock which is attached to a female-female luer lock to transfer the concentrated fat to an injection syringe.
Fill volumes	Volume = 5ml to 25ml	Volume = 5ml to 25ml
Principle of Operation	Fat is aspirated into syringe (i.e., centrifugation syringe) that has a removable handle. Shortened profile of syringe after removing the handle allows the syringe to fit in a standard centrifuge. Fat and supernatant material are separated via density-gradient separation.	Fat is aspirated into syringe (i.e., centrifugation syringe) that has a removable handle. Shortened profile of syringe after removing the handle allows the syringe to fit in a standard centrifuge. Fat and supernatant material are separated via density-gradient separation.
Centrifugation Protocol	1250 g-force 4 minutes	1250 g-force 4 minutes
Centrifuge	Generic centrifuge that has appropriate sized bucket.	Dedicated standard swinging bucket centrifuge
Sterilization Method of Procedure Pack	Ethylene-Oxide Gas (EtO)	Ethylene-Oxide Gas (EtO)
How Used	Single use only	Single use only

7. Performance Data

Design verification tests were performed based on the risk analysis and product requirements, and the results of these tests demonstrate that the Ranfac FATS Procedure Pack is adequately designed for the intended use indicated. Design verification tests included fluid transfer into and from the process disposable, centrifugation tests, data to support conformance with applicable requirements of ISO 7886-1:1993 and simulated use.

510(k) Summary (Page 4 of 4)

Biocompatibility testing have also been performed in compliance with ANSI/AAMI/ISO 10993-1: 2009 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and consistent with FDA's Blue Book Guidance G95 "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing. Results of this testing demonstrate that the materials used in the assembly of the FATS device are suitable for their intended use.

8. Clinical Data

Not applicable

9. Conclusion

Based on the similarities in indications for use, materials, design, principles of function, biocompatibility and sterilization between the Ranfac Fat Aspirate Transfer Syringe Procedure Pack, subject of this premarket notification and the predicate devices, the proposed subject device has been shown to be substantially equivalent to the predicate devices in accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act.