RANFAC CORP.
Attention: Barry Zimble
30 Doherty Ave.
Avon, MA 02322
Email Address: (b) (6)@ranfac.com

February 9, 2023

Re: BK220708 (Formally K162932)
Trade/Device Name: Ranfac Fat Aspiration Cannula
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QUB

Dear Mr. Zimble:

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 January 19, 2017. 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, Candace Jarvis at (240) 402-8315 or by email at Candace.Jarvis@fda.hhs.gov.

Sincerely,

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

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

January 19, 2017

Ranfac Corporation
Mr. Christopher Whelan
Senior Vice President
30 Doherty Avenue,
P.O. Box 635
Avon, Massachusetts 02322

Re: K162932
Trade/Device Name: Ranfac Fat Aspiration Cannula
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: October 18, 2016
Received: October 20, 2016

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 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" (21 CFR 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,

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)*
K162932

Device Name
Ranfac Fat Aspiration Cannula

Indications for Use *(Describe)*
The Ranfac Fat Aspiration Cannula is intended for use in aesthetic body contouring.
If 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)*

[X] 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.

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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."

510k Summary

Owner's Name and Address:

Ranfac Corp.
30 Doherty Avenue
Avon, MA 02322-0635
FDA Registration Number 1211566

Official Contact Person:

Christopher P. Whelan
Senior Vice President
Telephone: 508-588-4400 extension: 106
Facsimile: 508-584-8588
e-mail: cwhelan@ranfac.com

Date Summary Prepared: December 13, 2016

Device Trade Name: **Ranfac Fat Aspiration Cannula**

Common Name: Liposuction Cannula

Classification Name:

Suction lipoplasty system (MUU)
21 CFR § 878, General and Plastic Surgery Devices
Subpart E Surgical devices,
Sec. 878.5040 Suction lipoplasty system, Class II

Predicate Device:

510(k) Number	Predicate Description	Manufactured By
K060089	Tulip Disposable Cannulas	Tulip Medical

The materials used in the devices compare in this way:

Instrument	Ranfac Fat Aspiration Cannula	Tulip Disposable Cannulas
510(k) Number	K162932	K060089
Intended Use	The Ranfac Fat Aspiration Cannula are intended for use in aesthetic body contouring. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.	The Tulip Disposable Cannulas are intended for use in aesthetic body contouring.
Design	Sterile, Disposable	Sterile, Disposable
Performance Characteristics	Cannula designed to be attached to a Luer Lock type syringe. Cannula available in several diameters, lengths and tip configurations.	Cannulas are designed to be used with a syringe or syringe adaptor. They are available in various diameters, lengths and tip configurations.
Cannula Configuration	Hollow Cannula, with Closed End and Side Ports	Hollow Cannula, with Closed End and Side Ports
Ga. Size	11Ga., 13Ga. & 14Ga.	11Ga., 13Ga. & 14Ga.
Length	10cm, 12cm, 15cm, 20cm & 25cm	10cm, 12cm, 15cm, 20cm & 25cm
Sterilization	Supplied Sterile (Ethylene Oxide)	Supplied Sterile (Ethylene Oxide)
Materials: Cannula Handle Cannula	Plastic (ABS) ISO 9626 Stainless Steel with silicone coating	Plastic ISO 9626 Stainless Steel with hydrophilic coating

Background

The Ranfac Fat Aspiration Cannula are stainless steel cannula designed for connection to Luer Lock syringes or similar Luer Lock devices for aspiration. The cannula are made of stainless

steel, is silicone coated and are available in various diameters, lengths and tip configurations.

The Ranfac Fat Aspiration Cannula are single-use disposables, supplied sterile (Ethylene Oxide), and are packaged in a Tyvek® pouch.

Device Description: The Ranfac Fat Aspiration Cannula consist of silicone coated stainless steel tubing that is closed on the distal end and has fenestrations in the side wall to allow fat to be aspirated into the tubing. There is a Luer Lock compatible handle made of ABS plastic, molded to the cannula.

Intended Use: The Ranfac Fat Aspiration Cannula are intended for use in aesthetic body contouring. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

Technological Characteristics: The design, use and materials of the Ranfac Fat Aspiration Cannula and the predicate device are equivalent, in that all of the cannula are designed to be used for aesthetic body contouring and are fabricated of stainless steel. No new technology or change in indications for Use has been introduced by Ranfac Corp. in the manufacture of the Ranfac Fat Aspiration Cannula.

Clinical Data: Not applicable

Performance Testing:

Non-clinical Data:

Performance testing was conducted to demonstrate that the aspiration performance of the Ranfac Fat Aspiration Cannula was substantially equivalent to The Tulip Disposable Cannula. Testing performed:

- Aspiration of Distilled Water using the Ranfac Fat Aspiration Cannula with 30cc & 20cc syringes.
- Aspiration of Distilled Water using the Tulip Trivisonno Micro Harvester Cannula with 20cc & 30cc syringes.
- Aspiration of Distilled Water using the Tulip J. W. Little Harvester Cannula with 20cc & 30cc syringes.
- Aspiration of Distilled Water using the Tulip GEMS Carraway Harvester Cannula with 20cc & 30cc syringes.
- Aspiration of Silicone, Dow Corning 200 Fluid using the Ranfac Fat Aspiration Cannula with 30cc & 20cc syringes.
- Aspiration of Silicone, Dow Corning 200 Fluid using the Tulip Trivisonno Micro Harvester Cannula with 20cc & 30cc syringes.
- Aspiration of Silicone, Dow Corning 200 Fluid using the Tulip J. W. Little Harvester Cannula with 20cc & 30cc syringes.
- Aspiration of Silicone, Dow Corning 200 Fluid using the Tulip GEMS Carraway Harvester Cannula with 20cc & 30cc syringes.
- Aspiration of Pure Glycerin using the Ranfac Fat Aspiration Cannula with 30cc & 20cc syringes.
- Aspiration of Pure Glycerin using the Tulip Trivisonno Micro Harvester Cannula with 20cc & 30cc syringes.
- Aspiration of Pure Glycerin using the Tulip J. W. Little Harvester Cannula with 20cc & 30cc syringes.
- Aspiration of Pure Glycerin using the Tulip GEMS Carraway Harvester Cannula with 20cc & 30cc syringes.

Conclusion:

Based on the similarities in materials, design, manufacturing, principles of function, biocompatibility and sterilization between the Ranfac Fat Aspiration Cannula, subject of this premarket notification and the predicate device, we consider the Ranfac Fat Aspiration Cannula to be substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.