February 9, 2023

Syntr Health Technologies, Inc.
Attention: Nevine Erian
BQC Consultant, LLC
24341 Barbados Dr
Dana Poin, CA 92629

Re: BK220723 (Formally K203800)
Trade/Device Name: The SyntrFuge™ System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Ms. Erian:

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 July 2, 2021. 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.

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, Hosna Keyvan by email at hosna.keyvan@fda.hhs.gov .

Sincerely,

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

Enclosure

July 2, 2021

Syntr Health Technologies, Inc.
% Nevine Erian
Regulatory Consultant
BQC Consulting, LLC
24341 Barbados Dr.
Dana Point, California 92629

Re: K203800
Trade/Device Name: SyntrFuge System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: May 11, 2021
Received: May 13, 2021

Dear Nevine Erian:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203800

Device Name

SyntrFuge™ System

Indications for Use *(Describe)*

The SyntrFuge™ System is a sterile medical device used 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, 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.

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."

K203800 – 510(k) Summary

Submitter	**Syntr Health Technologies, Inc.** 5270 California Ave., Suite #300 Irvine, CA 92617, U.S. **Establishment Reg. No.** – 3017791237
Contact	Ahmed Zobi Chief Executive Officer **Phone** 949 732-4298 **E-Mail** azobi@syntrtech.com
Official Correspondent	Nevine Erian Regulatory Consultant **BQC Consulting, LLC** 24341 Barbados Dr. Dana Point, CA 92629 **Phone** (949) 370-7155 **Fax** (949) 240-8829 **E-mail** nevine@bqcconsulting.com
Date Prepared	June 27, 2021

- **Trade/Device Name** SyntrFuge™ System
- **Common Name** Suction Lipoplasty System
- **Classification Name** System, Suction, Lipoplasty
- **Regulation Number** 21 CFR 878.5040
- **Product Code** MUU

Predicate Devices

- AdiPrep™ Adipose Transfer System (Harvest Technologies Corp.) – K121005– ***Predicate***

Device Description

The SyntrFuge System is a sterile single use disposable medical device, comprised of three AdipoSets. Each AdipoSet is comprised of two AdipoChambers and one AdipoChip, two AdipoChambers attach to the AdipoChip by luer connectors.

The SyntrFuge™ System concentrates lipoaspirate, following a syringe vacuum liposuction method.

The SyntrFuge System is utilized in medical procedures where reinjection of adipose tissue into the same individual during the same surgical procedure is needed.

Indication for Use

The SyntrFuge™ System is a sterile medical device used 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, 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.

Safety and Performance Testing

Biocompatibility Testing

The SyntrFuge System was tested and meets the biocompatibility requirements of ISO 10993-1:2018 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process.

Test results demonstrated that the SyntrFuge System is non-cytotoxic, non-sensitizing, non-irritant, non-pyrogenic and has no systemic toxicity effects.

Performance Testing

The SyntrFuge™ System has undergone verification testing to ensure it meets product specification requirements. Verification testing consisted of the following:

- SyntrFuge System Design Verification Testing
- Cleaning Validation
- Cell Viability

- Distribution Simulation and Packaging Integrity Testing
- Usability Testing
- Sterilization Validation and Shelf-Life Testing

All testing met specifications. Bench test results allowed us to conclude that the SyntrFuge System meets its intended use.

Substantial Equivalence

The SyntrFuge System is substantially equivalent to the predicate device.

Substantial Equivalence Comparison of the SyntrFuge System to the Predicate Device

Attribute	SyntrFuge™ System	AdiPrep™ Adipose Transfer System (Predicate)
Classification & Regulation Number	System, Suction, Lipoplasty 21 CFR 878.5040	System, Suction, Lipoplasty 21 CFR 878.5040
Product Code	MUU	MUU
Indications for use		
Used in medical procedures involving the harvesting, concentrating and transferring of autologous adipose tissue harvested with a legally marketed lipoplasty system.	Yes	Yes
Intended for use in the following surgical specialities when concentration of harvested tissue is desired. ▪ Orthopedic surgery ▪ Arthroscopic surgery ▪ Neurosurgery ▪ Gastrointestinal surgery ▪ Urological surgery ▪ General surgery ▪ Gynecological surgery ▪ Thoracic surgery ▪ Laparoscopic surgery ▪ Plastic and reconstructive surgery	Yes	Yes

Attribute	SyntrFuge™ System	AdiPrep™ Adipose Transfer System (Predicate)
Technological Attribute		
Processing Pack Components	3 AdipoSets, comprised each of an AdipoChip and 2 AdipoChambers	Harvest AdiPrep Process Disposable unit, centrifuge tubes with filter, aspiration & fat injection cannula, fat injection syringes, skin puncture needles, and oil extraction syringe & needle.
Material Type	AdipoChip & AdipoChambers composed of medical grade resin.	Cannula & syringes composed of medical grade plastics.
Sterilization Method	Ethylene-Oxide (EO)	Ethylene-Oxide (EO)
Sterility Assurance	SAL 10^{-6}	SAL 10^{-6}
Design	AdipoSet/Chamber	Syringe
Mode of Operation	Centrifugation	Centrifugation
Processing Volume Capacity	5mL to 15mL	5 mL to 25 mL
Uses Laboratory Centrifuge System	Yes – SyntrFPU 360	Yes – SmartPrep2
Disposable or Reusable	Single Use, Disposable	Single Use, Disposable
Procedural Attribute		
Harvesting Method	Cannula	Cannula
Tissue Washing Media	Sterile Saline	Sterile Saline
Processing Output	Concentrated Adipose Tissue	Concentrated Adipose Tissue
Nucleated Cell Viability (%)	Mean = 87.8%	Mean = 83.5%
For Adipose Transfer	Yes	Yes
Environment of Use	Sterile Setting	Sterile Setting

The differences in product configuration between the SyntrFuge System and the AdiPrep Adipose Transfer System do not impact safety and effectiveness, as the SyntrFuge System

shares the same indications and achieves the same fat concentration as the predicate device.

Conclusion

Information provided in this application demonstrates that the SyntrFuge System is substantially equivalent to the predicate device. The SyntrFuge System has same indications for use and similar technological characteristics as the predicate device.