April 5, 2023

Stemics S.A.S
Attention: Catherine Gloster
Gloster Biomedical Internaltional, LLC
577 North Hope Avenue
Santa Barbara, CA 93110
Email address: (b) (6)

Re: BK220718 (Formerly K190386)
Trade/Device Name: The KTA Adipose Treatment Kit
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL, QUB

Dear Ms.Gloster:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative correction related to administrative letter dated February 9, 2023. Specifically, FDA is updating this administrative letter because the 510(k) holder name was stated incorrectly.

As stated in the administrative letter dated February 9, 2023, FDA updated your previous substantial equivalence (SE) determination letter dated October 10, 2019 because FDA 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-devicesthat-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,

Heather Lombardi, PhD
Acting Director
Office of Cellular Therapy and Human Tissue
Office of Therapeutic Products
Center for Biologics Evaluation and Research

Enclosure

October 10, 2019

Stemics S.A.S
% Catherine Gloster
President
Gloster Biomedical International, LLC
577 North Hope Avenue
Santa Barbara, California 93110

Re: K190386
Trade/Device Name: KTA Adipose Treatment Kit
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: February 15, 2019
Received: February 19, 2019

Dear Ms. Gloster:

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,

For Cindy Chowdhury, Ph.D., M.B.A.
Acting 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)*
K190386

Device Name
KTA Adipose Treatment Kit

Indications for Use *(Describe)*
The KTA Adipose Treatment Kit is intended for medical and surgical procedures involving autologous fat grafting that consists in:
-harvesting,
-centrifuging, and
-reinjecting autologous adipose tissue,
Within the same procedure.

The KTA Adipose Treatment Kit range consists in a family of products which are designed to harvest, process with minimal manipulation and reinject small – KTAMICRO, KTAEASY, KTAMY – to large –KTAMACRO, KTAMACROMED, KTASPIN – volumes of autologous fat in the following specialties:

Neurosurgery, Gastrointestinal Surgery, Urological Surgery, Plastic and 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.

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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STEMCIS

510(k) Summary

Submission Date: 10/6/2019

K190386

SUBMITTER INFORMATION

Company Name: STEMCIS SAS

Company Address: 2 rue du Professeur Paul Milleret
25000 Besançon
FRANCE

Contact Person: Stéphane Giraud
+33 967 501 298
Email: stephane.giraud@stemcis.com

DEVICE INFORMATION

Trade Name:	KTA Adipose Treatment Kit
Common Name:	Adipose Treatment Kit
Classification Name:	21CFR 878.5040
Device Class:	Class II
Product code:	MUU
Predicate Devices:	K081848 Lipose Fat Transfer System K121005 Harvest AdiPrep™ Adipose Transfer System
Device Description:	The KTA Adipose Treatment Kit consists of a sterile (EtO) single use disposable pack used for the aspiration, harvesting, centrifuging and reinjection of autologous adipose tissue during the same procedure. Each kit contains the necessary equipment such as syringes, cannulas, needles, containers, Luer Lock caps / connectors and a standard M8 single use nut for the centrifuge
Indications for Use:	The KTA Adipose Treatment Kit is intended for medical and surgical procedures involving autologous fat grafting that consists in: • Harvesting, • Centrifuging, and • Reinjecting autologous adipose tissue, Within the same procedure. The KTA Adipose Treatment Kit range consists in a family of products which are designed to harvest, process with minimal manipulation and reinject small – KTAMICRO, KTAEASY, KTAMY – to large –

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	KTAMACRO, KTAMACROMED, KTASPIN – volumes of autologous fat in the following specialties: Neurosurgery, Gastrointestinal Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery, Arthroscopic Surgery.
Performance Data:	Bench testing has been performed to demonstrate the substantial equivalence of the devices to the predicates. Bench testing included: shipping validation, real time and accelerated aging, usability testing, connections compatibility (connective forces and connection seal strength), maximum pressure and vacuum, dimensional analysis, resistance to corrosion, assembly testing, biocompatibility testing, and cell viability testing.
Technological Characteristics and Comparison to Predicate Device(s):	This submission describes the KTA Adipose Treatment Kit as compared to the predicate devices. Based on the intended use, design, materials, and technological characteristics presented in this premarket notification as summarized in the Table below, the STEMCIS KTA Adipose Treatment Kit has been shown to be substantially equivalent to the currently marketed predicate devices.

SUBSTANTIAL EQUIVALENCE COMPARISON CHART

Features	Subject device KTA range	K081848 Predicate	K121005 Predicate
Classification and regulation number	System, Suction, Lipoplasty 21CFR 878.5040	System, Suction, Lipoplasty 21CFR 878.5040	System, Suction, Lipoplasty 21CFR 878.5040
Product code	MUU	MUU	MUU

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Features	Subject device KTA range	K081848 Predicate	K121005 Predicate
Indications for use & intended use	The KTA Adipose Treatment Kit is intended for medical and surgical procedures involving autologous fat grafting that consists in: • Harvesting, • Centrifuging, and • Reinjecting autologous adipose tissue, Within the same procedure. The KTA Adipose Treatment Kit range consists in a family of products which are designed to harvest, process with minimal manipulation and reinject small – KTAMICRO, KTAEASY, KTAMY – to large – KTAMACRO, KTAMACROMED, KTASPIN – volumes of autologous fat in the following specialties: Neurosurgery, Gastrointestinal Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery, Arthroscopic Surgery.	The Lipose Fat Transfer System is intended to be used in the aspiration, harvesting, and reinjecting of autologous fat	The AdiPrep™ Adipose Transfer System is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. The AdiPrep™ system is used for concentrating adipose tissue harvested with a legally marketed system. The AdiPrep™ adipose transfer system is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired. Neurosurgery, Gastrointestinal Surgery, Urological Surgery, Plastic and reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery, Arthroscopic Surgery
Technological characteristics Processing pack components	Components-syringes with removable plunger, centrifuge tubes with filter, aspiration & fat injection cannula, fat injection syringes, skin puncture needles, and oil extraction syringe & needle. Cannula & syringes composed of medical grade plastics	Components-syringes with removable plunger, centrifuge tubes with filter, aspiration & fat injection cannula, fat injection syringes, skin puncture needles, and oil extraction syringe & needle	Components-syringes with removable plunger, centrifuge tubes with filter, aspiration & fat injection cannula, fat injection syringes, skin puncture needles, and oil extraction syringe & needle. Cannula & syringes composed of medical grade plastics
Sterilization method	Ethylene-Oxide Gas (EtO)	Gamma radiation	Ethylene-Oxide Gas (EtO)
Sterility Assurance Level	SAL 10^{-6} Shelf life: 3 years	SAL 10^{-6}	SAL 10^{-6}

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Features	Subject device KTA range	K081848 Predicate	K121005 Predicate
Packaging	Tyvek® sealing	Tyvek® sealing	Tyvek® sealing
Disposable or reusable	Single use, disposable	Single use, disposable	Single use, disposable
Biocompatibility	Biocompatible	Biocompatible	Biocompatible

NON-CLINICAL PERFORMANCE DATA

SAFETY BENCH TESTING

In accordance with ISO 10993-1, KTA Adipose Treatment Kit is categorized as an external communicating device with limited contact duration (<24 hours) with tissues. The biocompatibility tests recommended by ISO 10993-1 were performed. Results showed that the KTA Adipose Treatment Kit showed no cytotoxic potential, no delayed sensitization was observed and irritation response met the requirements and is considered non-irritant.

PERFORMANCE TESTING

In vitro testing was performed on the KTA Adipose Treatment Kit in accordance with ISO/IEC standards and/or internal procedures / European standards to assure reliable design and performance. In vitro testing included:

- Side testing applying to catheters / introducers (Cannulas 3.2 bars air pressure resistance),
- Connective forces,
- Connection seal strength,
- Maximum pressure and vacuum,
- Resistance to corrosion,
- Biocompatibility,
- Cell viability,
- Usability testing,

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- Assembly testing,
- Shipping test,
- Shelf-life (accelerated aging and real time).

All testing met their predetermined acceptance criteria.

CONCLUSION

KTA Adipose Treatment Kit is substantially equivalent to the predicate devices in Indications for Use, composition and design. It is as safe and as effective as the predicate. STEMCIS considers KTA Adipose Treatment Kit to be substantially equivalent to the predicate devices.