THIEBAUD SAS
Attention: Persat Jean-Charles
2 Impasse Des Primbois
Margencel
Haute-Savoie 74200, France
Email Address:(b) (6)@thiebaud.fr

February 9, 2023

Re: BK220702 (Formally K142073)
Trade/Device Name: ST'RIM
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QUB

Dear Mr. Jean-Charles:

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 April 29, 2015. 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

April 29, 2015

Thiebaud SAS
% Ms. Patsy J. Trisler, JD, RAC
Trisler Consulting
5600 Wisconsin Avenue, #509
Chevy Chase, Maryland 20815

Re: K142073
Trade/Device Name: st'rim™
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: March 16, 2015
Received: March 19, 2015

Dear Ms. Trisler:

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" (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)*
K142073

Device Name
st'rim™

Indications for Use *(Describe)*
The st'rim™ fat tissue harvest and injection cannula set is intended for use in aesthetic body contouring.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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."

510(k) SUMMARY— *st'rim™*

K142073

Submitter Name:	Thiebaud SAS
Submitter Address:	2 impasse des primbois 74200 Margencel France
Mailing address:	B.P. 160-F-74204 Thonon-les-Bains CEDEX
Contact Person:	Jean-Charles Persat, MD, Ph.D., President
Phone Number: Fax Number:	33 (0)4 50 72 70 80 33 (0)4 50 72 54 44
Date Prepared:	March 16, 2015
Device Trade Name:	st*'rim*™
Device Class:	II
Classification Number:	21 CFR 878.5040
Classification Name:	Suction Lipoplasty System
Product Code:	MUU
Predicate Device(s):	K060089, Tulip Disposable Cannulas, Cell Bio-Systems, Inc.
Statement of Intended Use:	The st'*rim*™ fat tissue harvest and injection cannula set is intended for use in aesthetic body contouring.
Device Description:	The st'*rim*™ set consists of one tissue harvesting cannula, three injection (application) cannulas, two incision needles, all made of stainless steel, and a capped double-ended female Luer Lock connector for transfer of the fat tissue from the collection syringe to an injection syringe. The body contacting material is medical grade stainless steel and the contact duration is short-term. All components are provided in a preformed plastic tray. The set is a sterile, single-use device.

Summary of Testing:	Laboratory testing of the st*'rim*™ Luer Lock connectors was performed to evaluate gauging, liquid and air leaking, separation force, unscrewing torque, ease of assembly, resistance to overriding and stress cracking. Packaging, sterilization and shelf life information and testing results were provided in the 510(k). The device set has been validated for a shelf life of 5 years. Biocompatibility testing according to ISO 10993: Parts 5, 10 and 11 was performed, and reports were included in the 510(k).
Comparison to the Predicate Devices:	The st*'rim*™ device set has the same intended use and the same principles of operation as the Tulip Disposable Cannulas predicate. Both are intended for harvesting (aspiration) and re-injecting autologous fat tissue. Both devices are made of stainless steel. The technological differences include length and diameter of the cannulas and a coating on the Tulip predicate while the st'*rim*™ is uncoated. Sterilization methods also are different: st'*rim*™ is EtO sterilized, while the Tulip is E-beam sterilized. None of these differences raise new questions of safety or effectiveness.
Conclusion regarding Substantial Equivalence:	The comparisons and data presented in the 510(k) lead to the conclusion that the st*'rim*™ device set is substantially equivalent to the predicate device.