Puregraft LLC
Olivia Kim
RA/QA Director
420 Stevens Avenue, Suite 220
Solana Beach, California 92075

June 9, 2021

Re: K200168
Trade/Device Name: Dermapose Access
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Olivia Kim:

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 22, 2020. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

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

April 22, 2020

Puregraft LLC
Olivia Kim
RA/QA Director
420 Stevens Avenue, Suite 220
Solana Beach, California 92075

Re: K200168
Trade/Device Name: Dermapose Access
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: January 21, 2020
Received: January 23, 2020

Dear Olivia Kim:

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,

Joseph A. Nielsen

Digitally signed by Joseph A. Nielsen
DN: cn=Joseph A. Nielsen, o=FDA, ou=FDA/CDRH/ODE/DSD/PRSB1, email=joseph.nielsen@fda.hhs.gov, c=US
Date: 2020.04.22 08:53:32 -04'00'

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)*
K200168

Device Name
Dermapose Access

Indications for Use *(Describe)*
The Dermapose Access fat harvest system 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.

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Office of Chief Information Officer
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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."

510(k) Summary

Submitter Information

Applicant Name: Puregraft LLC
420 Stevens Avenue, Suite 220
Solana Beach, CA 92075 USA

Company Contact: Olivia Kim
RA/QA Director
Phone: (858) 386-4140
Fax: (858) 217-5134
Email: okim@puregraft.com

Date Prepared: April 20, 2020

Device Information

Submission Number: K200168
Trade or Proprietary Name: Dermapose™ Access
Common Name: Suction lipoplasty system
Device Classification Name: System, Suction, Lipoplasty
Product Code: MUU
Regulatory Class: Class II
Classification Regulation: 21 CFR 878.5040
Panel: General & Plastic Surgery

Predicate Device

st'rim, K142073, Thiebaud SAS

Indications for Use

The Dermapose™ Access fat harvest system is intended for use in aesthetic body contouring.

Device Description

The Dermapose™ Access is a pre-assembled, sterile, single use system intended to assist the harvesting of autologous fat from a patient for aesthetic body contouring. It creates a guided incision for cannula introduction at a controlled depth (10 mm) under the skin for the purpose of small volume adipose tissue harvest.

The following are provided sterile with the Dermapose™ Access:

- A pre-assembled polycarbonate housing with a linear needle guidance system and a 12G x 51 mm lancet point needle to allow passage of a 14G cannula through the bore;
- A 14G x 150 mm Harvesting/Tumescent Cannula; and
- A silicone tube set with regulator valve, which connects to a user-provided vacuum source

The Dermapose™ Access is also intended to be used with a user-provided vacuum pump capable of at least 18 inHg (60 kPa) of vacuum in order to lift the patient's skin into the guide cavity. The pump should have a standard barb fitting of approximately ¼ inch. The use of a collection canister is recommended but is not necessary as fluid should not enter the tubing. To protect the pump from possible fluid ingress, the Dermapose™ Access includes a protective filter.

Technological Characteristics

The Dermapose™ Access is substantially equivalent to the predicate device, st'rim. A comparison of technological characteristics is provided in the table below. Both the subject device and the predicate device provide a method of cannula introduction for harvesting autologous adipose tissue. In addition, both the subject and predicate devices are provided sterile (via ethylene oxide) and intended for single use.

Device Name	**Subject Device Dermapose™ Access**	**Predicate Device St'rim (K142073)**	**Similarity**
Indications for Use	The Dermapose™ Access fat harvest system is intended for use in aesthetic body contouring.	The st'rim™ fat tissue harvest and injection cannula set is intended for use in aesthetic body contouring.	Identical
User Environment	Physician	Physician	Identical
Design Concept	Guided needle and cannula kit	Assorted needle and cannula kit	**Different**
Components	• 14G Harvest/Tumescent cannula • 12G incision needle housed in a linear guidance and vacuum-assisted skin hold system. • A silicone tube set for connection of vacuum	• 14G Harvest/Tumescent cannula • 14G incision needle • 21G injection cannula (short) • 21G injection cannula (long) • 21G incision needle • Luer-to-luer connector	**Different**
Method of Harvesting	Cannula (provided) and Syringe (user-provided)	Cannula (provided) and Syringe (user-provided)	Identical
Incision	Guided incision	Non-guided incision (physician pinch)	**Different**
Source of Harvest Energy	None - Manual by operator	None - Manual by operator	Identical
Source of Skin Hold Energy	User provided vacuum source	None - Manual by operator (pinch)	**Different**
Device performs Harvesting	No – requires syringe capable of holding vacuum	No – requires syringe capable of holding vacuum	Identical

Mechanical operation (entry)	Needle incision followed by concentric cannula introduction, then needle removal	Needle incision, then needle removal, followed by cannula introduction	Similar
Mechanical operation (harvest)	Requires syringe capable of holding vacuum, motion is back and forth and sweeping about entry point	Requires syringe capable of holding vacuum, motion is back and forth and sweeping about entry point	Identical
Mechanical operation (process)	Not part of system	Not part of system	Identical
Mechanical operation (delivery)	Injection via small syringes and injection cannula (not included)	Injection via small syringes (not included) and injection cannula (included)	Similar
Construction	Preassembled except for luer connections	Preassembled except for luer connections	Identical
Sterility	Supplied sterile for single use	Supplied sterile for single use	Identical
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical
Sterility Assurance Level	SAL = 10^{-6}	SAL = 10^{-6}	Identical
Biocompatibility	Biocompatible	Biocompatible	Identical

Performance Testing

The Dermapose™ Access was tested in accordance with established protocols and met the acceptance criteria for all tests performed.

Performance testing included:

- Skin Puncture Test: Evaluated the ability to penetrate skin using the Dermapose™ Access.
- Reliability Test: Evaluated the reliability of the Dermapose™ Access.
- Skin Hold and Needle Depth Analysis: Evaluated the performance of the Dermapose™ Access to hold and puncture skin.
- Cannula Analysis: Evaluated the laboratory testing of the cannula provided with the Dermapose™ Access.

Biocompatibility testing for the Dermapose™ Access was performed in accordance with the requirements of ISO 10993-1:2018 for external communicating devices having contact < 24 hours. In all instances, the test articles were found to be biocompatible. The battery of testing included the following tests:

- Cytotoxicity per ISO 10993-5:2009
- Sensitization per ISO 10993-10:2010
- Intracutaneous per ISO 10993-10:2010
- Acute Systemic Toxicity per ISO 10993-11:2017
- Pyrogen Testing per ISO 10993-11:2017
- Determination of Extractable Elements per ISO 10993-18:2005

Human Factors and Usability Engineering was evaluated. The Dermapose™ Access was found to be safe and effective for the intended users, uses, and use environments.

Sterilization of the Dermapose™ Access is conducted via the Single Lot Release Method by Ethylene Oxide according to Annex E: Single Lot Release of ISO 11135:2014/Amd.1:2018.

The Dermapose™ Access has an expiry date of 24 months based on integrity testing conducted post completion of accelerated aging and ISTA 2A ship testing.

Statement of Substantial Equivalence

Based on the information contained in this submission, it is concluded that the Dermapose™ Access is substantially equivalent to the predicate device, st'rim. The Dermapose™ Access has the same indications for use, as well as similar technological characteristics and principles of operation as its predicate device. Thus, the Dermapose™ Access is substantially equivalent to the st'rim.