February 9, 2023

Puregraft LLC
Attention: Olivia Kim
Bimini Health Tech
420 Stevens Ave, Suite 220
Solana Beach, CA
Email address: (b) (6)@purgraft.com

Re: BK220720 (Formally K193363
Trade/Device Name: The Demapose Refresh
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Ms. 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 14, 2020. 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

April 14, 2020

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

Re: K193363
Trade/Device Name: Dermapose Refresh
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: November 16, 2019
Received: December 4, 2019

Dear Ms. 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,

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)*
K193363

Device Name
Dermapose Refresh

Indications for Use *(Describe)*
The Dermapose Refresh is a sterile medical device intended for the closed-loop processing of lipoaspirate tissue 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 and affiliated organ surgery, 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)*

☒ 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."

PUREGRAFT

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: November 27, 2019

Device Information

Trade or Proprietary Name:	Dermapose™ Refresh
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

Lipogems System, K171135, Lipogems International SpA

Indications for Use

The Dermapose™ Refresh is a sterile medical device intended for the closed-loop processing of lipoaspirate tissue 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 and affiliated organ surgery, 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 reimplanted, the harvested fat is only to be used without any additional manipulation.

PURE GRAFT

Device Description

The Dermapose™ Refresh is a sterile, single use microsizing syringe system intended for the harvesting, concentrating, and transferring of autologous fat tissue back to the same patient when the transfer of harvested adipose tissue is desired. It consists of a 50 mL vacuum-lock syringe with a built-in, 800 µm filter for screening the tissue particle size to allow for easier injection through small, 18-21G injection cannulas. For optimum performance, Dermapose™ Refresh should be used in conjunction with the Dermapose™ Refresh Stand, which is a reusable, autoclavable component designed to hold the syringe securely during use.

The Dermapose™ Refresh is comprised of the following:

1. 50 mL polycarbonate harvesting and processing syringe unit preassembled with a 30 mL polycarbonate output syringe
2. Two 30 mL syringes
3. Three luer caps
4. Luer-to-luer adapter

The Dermapose™ Refresh is also intended to be used with Lactated Ringer's solution, injection syringes (1 or 3 mL recommended), injection cannulas (18-21G recommended), and luer-lock harvest cannula (14G recommended) which are provided by the user. Dermapose™ Refresh should be used in conjunction with the 510(k)-exempt Dermapose™ Refresh Stand.

Technological Characteristics

The Dermapose™ Refresh is substantially equivalent to the predicate device. A comparison of technological characteristics is provided in the table below. Both the subject device and the predicate device provide a method of harvesting, concentrating, and transferring of autologous adipose tissue. In addition, both the subject and predicate devices are pre-assembled systems which are provided sterile (via ethylene oxide) and intended for single use.

Device Name	**Subject Device** **Dermapose™ Refresh**	**Predicate Device** **Lipogems System (K171135)**
Indications for Use	The Dermapose™ Refresh is a sterile medical device intended for the closed-loop processing of lipoaspirate tissue 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 and affiliated organ surgery, urological surgery, general surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and plastic and	The Lipogems System is a sterile medical device intended for the closed-loop processing of lipoaspirate tissue 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 and affiliated organ surgery, urological surgery, general surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and plastic and

PURE GRAFT

	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 reimplanted, the harvested fat is only to be used without any additional manipulation.	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.
User Environment	Physician	Physician
Design	Syringe	Canister
Construction	Preassembled	Preassembled
Components	• 50 mL polycarbonate harvesting and processing syringe unit with vacuum lock and 30 mL output syringe containing a two-stage sieve filter on the inlet • Two 30 mL polypropylene luer-lock syringes • Three luer caps • Luer-to-luer adapter	• ABS processing unit containing 5 stainless steel spheres and 2 stainless steel sieve filters • Input washing line • Access port for loading material • Drain Line • Access Port for discharge of processed material • Bag for collecting waste
Device Size Variations	50 mL syringe	LGD 60 (60 mL capacity), LGD 240 (240 mL capacity)
Method of Harvesting	Cannula	Cannula
Source of Energy	None - Manual by operator	None - Manual by operator
Device performs Harvesting	Yes – Syringe generated vacuum-lock	No –syringe capable of holding vacuum provided in kit
Mechanical operation	Manual shaking of syringe	Manual shaking of canister (stainless steel spheres)
Device ports	2 ports: load/wash/drain port (combined); outlet valve	4 ports: load valve, wash feeding line, drain line, outlet valve
Tissue Washing Media	Lactated Ringer's	Physiological saline
Filter/mesh	1000 and 800 micron mesh at outlet – collected adipose tissue passes though both	2000 micron mesh at inlet and 1000 micron mesh at outlet – collected adipose tissue passes through both.
Sterility	Supplied sterile for single use	Supplied sterile for single use
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Sterility Assurance Level	SAL = 10^{-6}	SAL = 10^{-6}
Biocompatibility	Biocompatible	Biocompatible

PURE GRAFT

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

Performance testing included:

- Nucleated Cell Viability: Evaluated the nucleated cell viability using a Luna-Stem Automated Fluorescence Cell Counter.
- Tissue Composition: Evaluated the adipose tissue layer and fluid layer after adipose tissue was processed using the Dermapose™ Refresh.
- System Leak: Evaluated the ability of the Dermapose™ Refresh to hold vacuum (prevent system leak) via a stationary test and a side load test.
- Mechanical Test: Evaluated the mechanical connection testing of the Dermapose™ Refresh.

Biocompatibility testing for the Dermapose™ Refresh 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
- Determination of Extractable Elements per ISO 10993-18:2005
- Pyrogen Testing per ISO 10993-11:2017

Sterilization of the Dermapose™ Refresh 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™ Refresh 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™ Refresh is substantially equivalent to the predicate device, Lipogems System. The Dermapose™ Refresh has the same indications for use, as well as similar technological characteristics and principles of operation as its predicate device. Thus, the Dermapose™ Refresh is substantially equivalent to the Lipogems System.