INGENERON, INC.
Attention: Anita Kadala
8205 El Rio St.
Houston, TX 77054
Email Address: akadala@ingeneron.com

February 9, 2023

Re: BK220701 (Formally K141713)
Trade/Device Name: SMARTGRAFT 200 SYSTEM
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Ms. Kadala:

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 October 28, 2014. 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, Julia Russell at 240-704-0618 or by email at Julia.Russell@fda.hhs.gov.

Sincerely,

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

Enclosures

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

October 28, 2014

InGeneron Incorporated
Ms. Anita Kadala
Chief Executive Officer/General Counsel
8205 El Rio
Houston, Texas 77054

Re: K141713
Trade/Device Name: SmartGraft™ 200 System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: October 7, 2014
Received: October 10, 2014

Dear Ms. Kadala:

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)*
K141713

Device Name
SmartGraft™ 200

Indications for Use *Describe)*
The SmartGraft™ 200 system is intended to be used in medical procedures involving the harvesting, centrifugation and transferring of autologous adipose tissue. The SmartGraft™ 200 system is used for concentrating adipose tissue for aesthetic body contouring, and for tissue that has been harvested with a legally marketed lipoplasty system.

The SmartGraft™ 200 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, and
- 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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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

Date Summary Prepared: 07 October 2014

Applicant/Sponsor:
InGeneron, Inc.
8205 El Rio
Houston, TX 77054

Contact Person:
Anita Kadala – CEO/General Counsel
Tel: 713-440-9900
FAX: 713-715-5454
Email: AKadala@ingeneron.com

Device Trade Name: SmartGraft™ 200 System

Common Name: Suction Lipoplasty System

Classification Name: Suction Lipoplasty System, Class II

Regulation: 21 CFR 878.5040, Suction Lipoplasty System

Product Code: MUU

Legally Marketed Devices To Which Substantial Equivalence is Claimed:
K100114 Vortech™ Adipose Transfer System, Biomet Biologics, Inc. and,
K121005 AdiPrep™ Adipose Transfer System from Harvest Technologies Corp.

Device Description: The SmartGraft™ 200 System is a disposable process pack to be used with the InGeneron Tissue Processing Unit (centrifuge). The process pack is a collection of sterile single-use off-the-shelf and proprietary components used during the process of harvesting, centrifugation, and transferring of autologous adipose tissue. It is intended for the concentration of aspirated adipose tissue for subsequent transfer during the same procedure.

Indication For Use: The SmartGraft™ 200 System is intended to be used in medical procedures involving the harvesting, centrifugation and transferring of autologous adipose tissue. The

SmartGraft™ 200 System is used for concentrating adipose tissue for aesthetic body contouring, and for tissue that has been harvested with a legally marketed lipoplasty system.

The SmartGraft™ 200 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

Substantial Equivalence: The SmartGraft™ 200 System is believed to be substantially equivalent to the two referenced legally marketed predicate devices in that it has the same intended use, same operating principles and same function within the medical procedure, uses equivalent polymeric materials of construction, are all provided as sterile single-use disposables. The SmartGraft™ 200 device is sterilized using the same sterilization method as one referenced legally marketed predicate device. Substantial equivalence to a legally marketed predicate device in reference to biocompatibility for the intended use was determined using a recognized standard. The SmartGraft™ 200 System and both referenced legally marketed predicate devices are intended to be used for the same application across the same range of surgical specialties.

Technological Characteristics:

The SmartGraft™ 200 System is substantially equivalent to the two legally marketed predicate devices cited based on technological characteristics. The SmartGraft™ 200 and the two legally marketed predicates cited all are used in the concentration of adipose tissue harvested with legally marketed lipoplasty systems. All three are single-use devices made of medical-grade polymer materials. The

SmartGraft™ 200 device and at least one other predicate are tested for biocompatibility to ISO 10993. All three are sterilized using standard sterilization methods for sterile single-use devices. The SmartGraft™ 200 device and one predicate device utilize EO gas sterilization, whereas the other predicate device uses gamma irradiation for sterilization. All three devices utilize a centrifuge-like device using relatively low g-force for short periods of time for concentration of adipose tissue for transfer. The volume of adipose tissue processed by the SmartGraft™ 200 System is essentially identical to one of the predicate devices. Both of these volumes are larger than the volume processed by the other predicate device.

Bench Testing:

Determination of substantial equivalence was substantiated by a tabular specification comparison between the SmartGraft™ 200 and the two legally marketed predicate devices, and through two non-clinical studies involving only the SmartGraft™ 200 system. Both usability of the system according to Instructions for Use, and operation of the system to produce concentrated adipose tissue from lipoaspirate were tested. Concentrated adipose tissue produced using the SmartGraft™ 200 system was investigated further evaluating the nucleated cell viability of the concentrated adipose tissue compared to unprocessed adipose tissue. The results of the viability evaluation indicate that the SmartGraft™ 200 system does not adversely impact viability of the adipose tissue. Impact of the SmartGraft™ 200 system on cell viability is then substantially equivalent to that of predicate devices. A specification comparison between the SmartGraft™ 200 System and predicate devices was used to make a determination of substantial equivalence. The specification comparison shows that all three use low g-force centrifugation for a short period of time as an operating principle to obtain concentrated lipoaspirate. The Usability and Clinical Evaluation protocols and corresponding reports indicate that that the SmartGraft™ 200 System performs to specification, and can be operated successfully with the Instructions for Use provided.