Millennium Medical Technologies Inc./DBA Cellmyx
Attention: Jacqueline Hauge
Regulatory Consultant
37743 175th Ave
Avon, MN 56310
Email address: Jacqueline.Hauge@gmail.com

February 9, 2023

Re: BK220726 (Formally K210528)
Trade/Device Name: IntelliFat Disposable Adipose Tissue Harvesting and Transfer Kit, IntelliFat Body On Demand (BOD) Kit
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL, QUB

Dear Ms.Hauge:

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 March 16, 2022. 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

March 16, 2022

Millennium Medical Technologies Inc (DBA Cellmyx)
% Jacqueline Hauge
Regulatory Consultant
Cellmyx
37743 175th Avenue
Avon, Minnesota 56310

Re: K210528
Trade/Device Name: IntelliFat Disposable Adipose Tissue Harvesting and Transfer Kit
IntelliFat Body On Demand (BOD) Kit
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: January 28, 2022
Received: January 31, 2022

Dear Jacqueline Hauge:

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 Deborah Fellhauer, RN, BSN
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210528

Device Name
intelliFat™ Disposable Adipose Tissue Harvesting and Transfer Kit
intelliFat™ BOD Kit

Indications for Use *(Describe)*

The intelliFat Disposable Adipose Tissue Harvesting and Transfer or BOD Kit 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.

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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

I. Submitter

Date Prepared: March 15, 2022

Name and Address: Cellmyx
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Carlsbad, CA 92011

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Secondary Contact: Michelle Nguyen
Quality Assurance and Regulatory Manager, Cellmyx
6352 Corte de Abeto, Suite A
Carlsbad, CA 92011
Phone: (949) 215-8560
Email: michelle@cellmyx.com

II. Device Information

FDA Product Code:	MUU
FDA Regulation Number:	21 CFR 878.5040
FDA Classification Name:	System, Suction, Lipoplasty
Classification Panel:	General and Plastic Surgery
Common Name:	Lipoplasty System
FDA Classification:	Class II
Device Name:	intelliFat™ Disposable Adipose Tissue Harvesting and Transfer Kit intelliFat™ Body On-Demand (BOD) Kit

III. Predicate Information

Predicate	510(k) Number	Trade Name	Submitter
Primary	K161636	Lipogems System	Lipogems International SpA
Reference	K162932	Ranfac Fat Aspiration Cannula	Ranfac Corp.
Reference	K113255	Puregraft 850/PURE System	Cytori Therapeutics, Inc.

IV. Device Description

The intelliFat Disposable Adipose Tissue Harvesting and Transfer and intelliFat BOD Kits are sterile single-use, disposable suction lipoplasty systems that are intended for closed-loop processing of lipoaspirate tissue in various medical procedures involving harvesting and transferring autologous adipose tissue. These kits contain stand-alone components that are assembled by the physician user. Primary components include: cannulae, filters, resizer, luer adapters, and syringe caps. The intelliFat Kits accommodate minimal handling of adipose tissue. These devices may be used in combination with FDA-cleared device such as syringes.

V. Indication for Use

The intelliFat Disposable Adipose Tissue Harvesting and Transfer or BOD Kit 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.

VI. Comparison of Technological Characteristics

Technological Characteristics	Predicate Device	Reference Devices		Subject Device
	Lipogems System	Ranfac Fat Aspiration Cannula	Puregraft 850/PURE System	IntelliFat™ Kits
Regulatory Information				
510(k) Number	K161636	K162932	K113255	This submission
Device Name	Lipogems System	Ranfac Fat Aspiration Cannula	Puregraft 850/PURE System	intelliFat Disposable Adipose Tissue Harvesting and Transfer Kit, intelliFat BOD Kit
Manufacturer	Lipogems International SpA	Ranfac Corp.	Cytori Therapeutics, Inc.	Cellmyx
Common Name	Lipoplasty System	Ranfac Fat Aspiration Cannula	Puregraft 850/PURE System	Lipoplasty System
Regulation Number	21 CFR 878.5040	21 CFR 878.5040	21 CFR 878.5040	21 CFR 878.5040
Device Class	Class II	Class II	Class II	Class II
Product Code	MUU	MUU	MUU	MUU
Classification Panel	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery
Intended Use				
Indications for Use Statement	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	The Ranfac Fat Aspiration Cannula are intended for use in aesthetic body contouring. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.	The Puregraft 850/PURE System is indicated for use in the harvesting, filtering and transferring of autologous fat tissue for reinjecting back into the same patient for aesthetic body contouring.	The intelliFat Disposable Adipose Tissue Harvesting and Transfer or BOD Kit 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

Technological Characteristics	Predicate Device	Reference Devices		Subject Device
	Lipogems System	Ranfac Fat Aspiration Cannula	Puregraft 850/PURE System	IntelliFat™ Kits
	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.			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.
Technological Characteristics				
System	Closed loop	-	Closed loop	Closed loop
Construction	Preassembled	-	-	Assembly by user
Use and Sterility	Single-use, sterile	Single-use, sterile	Single-use, sterile	Single-use, sterile
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Gamma irradiation	Gamma Radiation
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Biocompatible

510(k) Summary

Cellmyx

Technological Characteristics	Predicate Device	Reference Devices		Subject Device
	Lipogems System	**Ranfac Fat Aspiration Cannula**	**Puregraft 850/PURE System**	**IntelliFat™ Kits**
Mechanical Operation	Manual shaking of stainless-steel spheres through filtered chamber	-	Manually operated system that receive adipose tissue, filter the adipose tissue, and temporarily hold the adipose tissue until it is removed or placed into a syringe that delivers / re-injects the adipose tissue back into the same patient during the same surgical procedure	Manual transfer back and forth through filtered syringe
Source of Energy	None required	None required	None required	None required
Tissue Washing Media	Physiological saline	-	-	Physiological saline
Harvesting Cannula Ga. Size	13Ga.	11Ga., 13Ga. & 14Ga.	-	12Ga.
Harvesting Cannula Length	19cm	10cm, 12cm, 15cm, 20cm & 25cm	-	15cm
Filter / Mesh sizes	LGD 240 and LGD60: 2000 micron mesh at inlet and 1000 micron mesh at outlet - collected adipose tissue passes though both meshes	-	The Puregrafto 850 Bag contains two (2) filters that are continuous within the bag. The first filter is an 800 micron filter mesh and the second filter is a 74 micron filter mesh.	Filters: 100 micron and 300 micron Resizer: 500 micron

VII. Summary of Non-Clinical Testing and Risk Analysis

The performance of the device is entirely controlled by the user and is not predetermined by the device itself. The instructions for use advise the user on the proper user of the device.

Nonclinical testing included:

- Biocompatibility testing:
  - Cytotoxicity
  - Sensitization
  - Intracutaneous Reactivity
  - Acute Systemic Toxicity
  - Pyrogen
- Sterilization validation
- Packaging validation
- Nucleated cell viability

VIII. Clinical Testing

Clinical testing was not required to support a substantial equivalence determination for the intelliFat Kits.

IX. Conclusion

Based on the comparison of intended use and technological characteristics, Cellmyx has demonstrated that the intelliFat Kits are substantially equivalent to the predicate device.