Millennium Medical Technologies Inc.
Attention: Gregory Miles
Millennium Medical Technologies Inc./DBA Cellmyx
6352 Corte Del Abeto, Suite A
Carlsbad, CA 92011

February 9, 2023

Re: BK220711 (Formally K170449)
Trade/Device Name: Autoclavable Suction Jar with Luer Lock extension - 250 500 1000 2000 and 3000 ml; Autoclavable Suction Jar without Luer Lock extension - 1500 and 2500 ml; Sterile 1500 and 2500 Lids with Conical patient connection 6-10 and overflow protection
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Mr. Miles:

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 31, 2017. 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

March 31, 2017

Millennium Medical Technologies, Inc.
Mr. Jim Barley
Director of Regulatory Affairs
6352 Corte Del Abeto
Suite A
Carlsbad, California 92011

Re: K170449
Trade/Device Name: Autoclavable Suction Jar With Luer Lock Extension - 250, 500, 1,000, 2,000 And 3,000 Ml, Autoclavable Suction Jar Without Luer Lock Extension - 1,500 And 2,500 Ml, Sterile 1,500 And 2,500 Lids With Conical Patient Connection 6-10 And Overflow Protection
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: January 27, 2017
Received: February 15, 2017

Dear Mr. Barley:

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" (21 CFR 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,

Jennifer R. Stevenson -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)*

K170449

Device Name

- MMT Autoclavable Suction Jar with Luer Lock extension- 250, 500, 1,000, 2,000 and 3,000 ml,
- MMT Autoclavable Suction Jar – 1,500 and 2,500 ml
- MMT Sterile and non sterile 1,500 and 2,500 Lids with Conical patient connection 6-10 and overflow protection

Indications for Use *(Describe)*

The Millennium Medical Technologies, Inc. Autoclavable Suction Jars and Lids are used in conjunction with hospital or surgery center vacuum and/or cleared pumps, tubing and cannulas, for the collection of aspirated fat, for aesthetic body contouring. If the fat is untreated, it may be reinjected via a cleared injection apparatus.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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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."

MILLENNIUM MEDICAL TECHNOLOGIES, INC.

FAT COLLECTION AND TRANSFER DEVICES

510(k) Summary (As required by 21 CFR 807.92(a))

Applicant and Correspondent

Name:	Millennium Medical Technologies, Inc.
Address:	6352 Corte Del Abeto, Ste. A Carlsbad, CA 92011
Contact:	Greg Miles
Phone Numbers:	(949) 215-8560 (Voice)
Date of Preparation:	March 10, 2017

Manufacturer **Millennium Medical Technologies, Inc.**

6352 Corte Del Abeto, Ste. A
Carlsbad, CA 92011

Registration#: 2032809

Name of Device

Trade/Proprietary/Model Name:

- **MMT line of Collection Jars & Transfer Devices**
  - Autoclavable Suction Jars and Lids with Luer Lock extension and extraction tube - 250, 500, 1,000, 2,000 and 3,000 ml
  - Suction Jar without Luer Lock extension - 1,500 and 2,500 ml
  - Sterile 1,500 ml and 2,500 ml Lids with Liner and Conical patient connection 6-10 and overflow protection

Common Name:	Fat Collection and Transfer Devices
Classification Name:	Suction Lipoplasty System
Classification Regulation:	878.5040
Panel:	General and Plastic Surgery
Product Code:	MUU
Recognized Performance Std:	None

Device to Which New Device is Substantially Equivalent

Device Name:	Tissu-Trans Filtron
Manufacturer:	Shippert Medical Technologies, Inc.

MILLENNIUM MEDICAL TECHNOLOGIES, INC.

FAT COLLECTION AND TRANSFER DEVICES

Reference: K092482

510(k) SUMMARY (Continued)

Device Description

The Millennium Medical Technologies line of Fat Collection and Transfer Devices consist of the following:

1. Autoclavable Suction Jars and lids with Luer Lock extension and extraction tub - 250, 500, 1,000, 2,000 and 3,000 ml
2. Suction Jar without Luer Lock extension – 1,500 and 2,500 ml
3. Sterile 1,500 and 2,500 ml Lids with Conical patient connection 6-10 and overflow protection

The Millennium Medical Technologies Collection Jars are Suction Canisters molded from medical grade polycarbonate. The 250, 500, 1,000, 2,000 and 3,000 ml canisters have a stainless steel luer fitting at its base to facilitate the transfer of untreated fat back into the patient using a cleared injection apparatus. The 1,500 and 2,500 ml canisters are designed to interface with the Lid with Liner and do not have a fitting at the base of the canister. All of the Collection Jars are provided non-sterile and are autoclavable.

The Millennium Medical Technologies Small and Large Lids are molded from medical grade polypropylene and have various ports, medical grade silicone tubing and a liner to contain all waste. The Large Lid has a 6-10 tapered cone for the 2,500 ml canister and the Small Lid has a 6-10 tapered cone for the 1,500 ml canister. The Lids with Liner are provided sterile.

Statement of Intended Use

The Millennium Medical Technologies, Inc. Collection Jars and Lids are used in conjunction with hospital or surgery center vacuum and/or cleared pumps, tubing and cannulas, for the collection of aspirated fat, for aesthetic body contouring. If the fat is untreated, it may be re-injected via a cleared injection apparatus.

Summary of Technological Characteristics

The Intended Use statement of the MMT Collection Jars and Lids with Liners is identical to that of the predicate. The materials of construction used in the MMT Collection Jars and Lids with Liners are identical to those of the predicate device. Performance testing has demonstrated that the products' efficacy and effectiveness is substantially equivalent to the predicate device.

A comparison of the MMT Collection Jars and Lids with Liners to the predicate device, the Shippert Medical Technologies Collection Jars and Lids with Liners is given in Table 1

MILLENNIUM MEDICAL TECHNOLOGIES, INC.

FAT COLLECTION AND TRANSFER DEVICES

Parameter Description		Predicate Device: SMT Tissu Trans Filtron	Subject Device: MMT Fat Collection and Transfer System	Comparison of Subject Device to Predicate
Technological Characteristics	FDA Predicate #	K092482	K170449	N/A
	Product Code	MUU	MUU	Same
	Clearance Date	12/4/2009	TBD	N/A
	Indication for Use	The Tissu Trans Filtron is intended to be used with house vacuum and/or cleared pumps, tubing and cannulas, for the collection of aspirated fat, for aesthetic body contouring. If the fat is untreated, it may be re-injected via a cleared injection apparatus.	The Millennium Medical Technologies, Inc.(MMT) Fat Collection and Transfer Devices are intended to be used with house vacuum and/or cleared pumps, tubing and cannulas, for the collection of aspirated fat, for aesthetic body contouring. If the fat is untreated, it may be re-injected via a cleared injection apparatus.	Same
	Description	The Tissu Trans Fltron is provided in a sterile, two piece packaged assembly. The Tissu Trans Filtron. The Tissu Trans Filtron is a single-use, sterile, disposable device designed to utilize an FDA cleared house vacuum to create suction within the physician supplied hollow liposuction and remove subcutaneous fatty tissue from the patient and transport the autologous tissue into the collection canister.	The Millennium Medical Technologies Collection Jars are suction canisters molded from medical grade polycarbonate. The 250, 500, 1,000, 2,000 and 3,000 ml canisters are provided non-sterile and are autoclavable. Each Collection Jar has a stainless steel luer fitting at its base to facilitate the transfer of untreated fat back into the patient using a cleared injection apparatus. The 1,500 and 2,500 ml collection jars are also molded from medical grade polycarbonate and are used with the MMT Lids with Liners. The 1,500 and 2,500 ml collection jars are autoclavable. The Millennium Medical Technologies Small and Large Lids are molded from medical grade polypropylene and have various ports, medical grade silicone tubing and a liner to contain all waste. The Large Lid has a 6-10 tapered cone for the 2,500 ml canister and the Small Lid has a 6-10 tapered cone for the 1,500 ml canister. The Lids are provided sterile.	Similar and SE

MILLENNIUM MEDICAL TECHNOLOGIES, INC.

FAT COLLECTION AND TRANSFER DEVICES

Parameter Description		Predicate Device: SMT Tissu Trans Filtron	Subject Device: MMT Fat Collection and Transfer System	Comparison of Subject Device to Predicate
Specification	Autoclavable Collection Jars for Lids w/Liner	500, 1,000 and 2,000 Liners	1,500 and 2,500 Liners	SE
	Autoclavable Collection Jars	250, 500, 1,000, 2,000 and 3,000 ml	250, 500, 1,000, 2,000 and 3,000 ml	Same
	Collection Jar Lids	Large and Small Lids	Large and Small Lids	Same
Style	Collection Jar rim diameter	2 sizes	2 sizes	Same
	Design	Jar with handle	Jar with handle	Same
	Scale units	mL	mL	Same
	Port at base of Collection Jar	No	Yes	Different
Other Features	Method to separate waste from fat	Vacuum fat through filter	Gravity	Different
	Waste Jar required	Yes	No	Different
How Supplied	Non-Sterile	Collection Jars	Collection Jars	Same
	Sterile	Collection Jar with Lid and Filter	Lid with Bag Liner	Different

Brief description of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence.

- The following biocompatibility tests were conducted on the MMT Fat Collection and Transfer Devices:
  - ISO MEM Elution Using L-329 Mouse Fibroblast Cells
  - ISO Intracutaneous Irritation Test
  - ISO Acute Systemic Injection Test
  - ISO Guinea Pig Maximization Sensitization Test

MILLENNIUM MEDICAL TECHNOLOGIES, INC.

FAT COLLECTION AND TRANSFER DEVICES

- The MMT Fat Collection and Transfer Devices were tested for leakage and compatibility of Collection Jars with Lids and Liners. In addition, the accuracy of the MMT) Fat Collection and Transfer Devices was compared to the comparative predicate device.
- For the product supplied sterile, Millennium Medical conducted a Gamma Irradiation Sterilization Validation per the requirements of ISO 11137-1:2006;Amd. 1, 2013.

- For the autoclavable product;
  - A Cleaning Validation was performed in accordance with the AAMI TIR30:2011 Guidance document. The Cleaning Validation was conducted to ensure that once the device has been used, it can be properly cleaned for resterilization.
  - A Sterilization Validation for a gravity autoclave was conducted per the requirements of TIR N0. 12-2004 and ISO 17665-1:2006/(R) 2013. The product was prepared with a resistant organism at a population of 1.0 X 106 colony forming units (CFU), subjected to a gravity autoclave cycle at one half the intended time for resterilization, then sterility tested. In addition, the 10 minute default autoclave drying cycle was qualified.

Brief discussion of clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence.

Not applicable.

Conclusion drawn for the nonclinical and clinical tests

The MMT Fat Collection and Transfer Devices have the same intended use and technological characteristics as the predicate device, Shippert Medical Technologies. The materials of construction used in the MMT) Fat Collection and Transfer Devices are substantially equivalent to those of the predicate device. Performance testing has demonstrated the product's efficacy. The MMT) Fat Collection and Transfer Devices have been demonstrated to be substantially equivalent to the predicate device.