**April 5, 2023**

Jointechlabs, Inc.
Attention: Nathan Katz
108 South Wynstone Park Dr., Ste 114
North Barrington Illinois, 60010
Email Address: (b) (6) @jointechlabs.com

Re: BK 220716 (Formerly K182732)
Trade/Device Name: The JTL Tissue Processing Device
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Mr. Katz:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative correction related to administrative letter dated February 9, 2023. Specifically, FDA is updating this administrative letter because the 510(k) holder name was stated incorrectly.

As stated in the administrative letter dated February 9, 2023, FDA updated your previous substantial equivalence (SE) determination letter dated October 10, 2019 because FDA 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-devicesthat-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,

Heather Lombardi, PhD
Acting Director
Office of Cellular Therapy and Human Tissue
Office of Therapeutic Products
Center for Biologics Evaluation and Research

Enclosure

November 18, 2019

Jointechlabs, Inc.
Thomas Lawson
Director, Regulatory Affairs
8 Graystone Court
North Barrington, Illinois 60010

Re: K182732
Trade/Device Name: Jtl-250-01
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: October 15, 2019
Received: October 17, 2019

Dear Dr. Thomas Lawson:

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 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)*
K182732

Device Name
JTL-250-01 Tissue Processing Device

Indications for Use *(Describe)*
The JTL Tissue Processing Device is a sterile medical device intended for the 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 re-implanted, 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."*

# 510(k) Summary

## General Information

| | |
|---|---|
| Submitter | Jointechlabs, Inc. |
| 510(k) Number | K182732 |
| Address | 8 Graystone Court<br>North Barrington, IL 60010 |
| Correspondence Person | Thomas Lawson, PhD<br>Director, Regulatory Affairs |
| Contact Information | Email: drthomlawson@gmail.com<br>Phone: 510-206-1794 |
| Date Prepared | 15 October 2019 |

## Proposed Device

| | |
|---|---|
| Trade Name | Tissue Processing Device JTL-250-01 |
| Common Name | JTL-250-01 |
| Regulation Number and Classification Name | 21 CFR§878.5040 Suction Lipoplasty System |
| Product Code | MUU |
| Regulatory Class | II |

## Predicate Device

| | |
|---|---|
| Trade Name | LipoGems System |
| Common Name | LipoGems 240 |
| Premarket Notification | K161636 |
| Regulation Number and Classification Name | 21 CFR§878.5040 Suction Lipoplasty System |
| Product Code | MUU |
| Regulatory Class | II |
| Note: This predicate device has not been subject to a design-related recall. | |

## Device Description

The JTL-250-01 Tissue Processing Device is a centrifuge tube for processing lipoaspirate fat tissue that is intended for autologous homofunctional implant (lipofilling).

The device is a pre-assembled, single-use centrifuge tube composed of a collection upper chamber, intermediate chamber, and a lower chamber. The diameter of the JTL Tissue Processing Device is 4.2 inches at the top ring and 3.6 inches in the main body. It stands 4 inches tall. The device weighs less than 1 pound. The components of the device are made of biocompatible materials.

The device is sterilized by radiation and is intended for single use only.

The JTL Tissue Processing Device is to be used in a healthcare facility. It is to be used and in contact with patient tissue for less than 24 hours and is made of materials that are biocompatible.

**Indications for Use**

The JTL Tissue Processing Device is a sterile medical device intended for the 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 re-implanted, the harvested fat is only to be used without any additional manipulation.

Both the subject device and the predicate device have the same indication and intended use, which is to process lipoaspirate fat tissue intended for autologous homofunctional implant (lipofilling).

**Comparison of Technological Characteristics with the Predicate Device and Subject Device**

JoinTech Labs has identified the LipoGems System (K161636) as the predicate device. The JTL Tissue Processing Device is substantially equivalent to the predicate device based upon the following similarities:

1. The intended use of both the predicate device and the JTL Tissue Processing Device is to process lipoaspirate fat tissue, with the result being a homogeneous and micronized fraction of fat tissue;
2. Both devices have mechanics that facilitate mixing and filtering of the tissue to a point where the tissue can be implanted; and
3. Both devices are made from biocompatible materials.

Comparison of the JTL-250-01 Tissue Processing Device to the predicate device:

| | **Jointech Labs, Inc JTL-250-01 Proposed Device, K182732** | **Lipogems International SpA Lipogems System, K161636** |
|---|---|---|
| **Indications For Use** | The JTL Tissue Processing Device is a sterile medical device intended for the 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 re- implanted, the harvested fat is only to be used without any additional manipulation. | 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 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. |
| **Intended Use** | To process lipoaspirate fat tissue intended for autologous homofunctional implant (lipofilling) | To process lipoaspirate fat tissue intended for autologous homofunctional implant (lipofilling) |
| **Site of use** | Hospitals | Hospitals |
| | | |
| **Technical Features** | | |

| | | |
|---|---|---|
| Components | Pre-assembled centrifuge tube with filters for microfracturing of adipose tissue | Pre-assembled cylinder containing filters and stainless steel beads for microfracturing of adipose tissue<br>Syringes Tubing<br><br>Waste Collection Bag |
| System Concept | Closed Loop | Closed Loop |
| Fill Volume | Up to 120 mL of fat | Up to 120 mL of fat |
| Mechanics of Tissue Separation Action | Filtering and microfracturing by spinning the tube in a centrifuge so that the material separates as it moves through various filters | Filtering and microfracturing by physical shaking of the cylinder and then hanging the cylinder in reverse orientation so that the material moves through filters by gravity |
| Provided Sterile | Yes | Yes |
| Sterilizing agent | Radiation | Ethylene Oxide |
| Sterility Assurance Level | $10^{-6}$ | $10^{-6}$ |
| Single Use | Yes | Yes |
| Duration of use | ≤ 24 hours | ≤ 24 hours |
| Tissue contact materials | Compliant with ISO 10993 | Compliant with ISO 10993 |

**Performance Data**

The performance testing conducted establishes that the JTL Tissue Processing Device does not raise new questions of the safety or effectiveness.

**Biocompatibility testing**

The JTL Tissue Processing Device is manufactured from materials with a long history in medical devices and passed all tests:

- Cytotoxicity,
- Sensitization,
- Acute Systemic Toxicity, and
- Irritation.

**Electrical safety and electromagnetic compatibility (EMC)**

There are no electronics or electrical elements in this device.

**Software Verification and Validation Testing**

There is no software in this device.

**Mechanical Testing**

The mechanical testing of the subject device included:

- 12-month accelerated aging and package performance testing;
- Fat graft volume;
- Oil volume;
- Verification testing of the functional design outputs for the device; and
- Performance assessment of the JTL-250-01 and the LGD 240 devices with respect to production of fat tissue that is viable and able to be administered during surgical procedures.

**Animal Testing**

No animal testing of the subject device was necessary.

**Clinical Studies**

No clinical testing of the subject device was necessary.

**Conclusion**

The information submitted in this premarket notification confirms that the Tissue Processing Device raises no new questions of safety and effectiveness and that it is substantially equivalent to the predicate device.