BSL Co.

February 9, 2023

Attention: Jun Seok Lee
BSL Co., Ltd.
6-13, Chilsan-ro 237beon-gil
Gimhae-si, Gyeongsangnam-do, 51006 Republic of Korea

Re: BK220715 (Formally K172717)
Trade/Device Name: Automatic Tissue Processing Unit
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Mr. Lee:

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 May 25, 2018. 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

May 25, 2018

BSL Co.
% Peter Chung
President
Plus Global
300 Atwood
Pittsburgh, Pennsylvania 15213

Re: K172717
Trade/Device Name: Automatic Tissue Processing Unit
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: April 25, 2018
Received: April 25, 2018

Dear Mr. Chung:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172717

Device Name
Automatic Tissue Processing Unit

Indications for Use *(Describe)*
The Automatic Tissue Processing Unit is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. The Automatic Tissue Processing Unit is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The Automatic Tissue Processing Unit 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
Arthoscopic 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.

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
[as required by 807.92(c)]

1Applicant

1) Company: BSL Co.
2) Address: 6-13, Chilsan-ro 237beon-gil,Gimhae-si,Gyungsangnam-do, South Korea
3) Tel:82-55-328-9235
4) Fax: 82-55-328-9236
5) Prepared date: July 4, 2017
6) Contact person: Peter Chung,412-512-8802
7) Contact person address: 300 Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date: August 25, 2017

2. Device Information

1) Trade name: Automatic Tissue Processing Unit
2) Common name: Fat Concentration System
3) Regulation name: Suction Lipoplasty System
4) Product code: MUU
5) Regulation number: 878.5040
6) Class of device: Class II
7) Panel: General and Plastic surgery

3. The legally marketed device to which we are claiming equivalence
K121005, AdiPrep™ Adipose Transfer System

4. Device description
The fat harvested by liposuction, called as lipoaspirates, contains fat tissues, bloody impurities and tumescent solution. The harvested lipoaspirates are not appropriate for autologous fat transfer without removal of the bloody impurities and tumescent solution containing anesthetic agent, anti-coagulant agent, antibiotics etc. In addition, the harvested fat tissues are not homogenous and contain uneven fibrotic tissues. So, for the purpose of in autologous fat transfer surgical technique, ACPU kit is designed and developed for harvest of the fine homologous adipose tissue in a sterile and closed way. ACPU needs to be centrifuged by using exclusive centrifuge (ACS Combo-A-Centrifuge/Product code: JQC) and the kits are single-use only.

5. Intended Use:
The Automatic Tissue Processing Unit is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. The Automatic Tissue Processing Unit is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The Automatic Tissue Processing Unit 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

6. Performance data:

1) Bench test were performed. Bench testing included biocompatibility, mechanical testing, sterility testing including EO residues. The tests demonstrated that the device performs in a substantially equivalent manner to the predicate device. The following bench testing is performed to demonstrate the functionality is substantially equivalent.

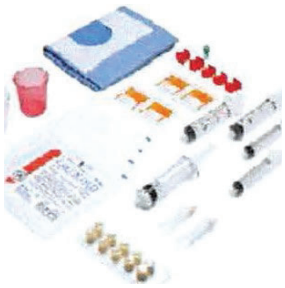
Test item	Requirements	Results
Appearance	It should not be defects in flaws, breakage or contamination of foreign objects.	Pass
Measurement	When measuring with Vernier calipers, according to the dimension of 'shape and structure' part, the stated should be within ±5 %.	
Leakage	When tested according to the test method, there should be no leakage.	
Residuals of cleaning liquid	When tested according to the test method, the residuals of cleaning liquid should be less than 20 ml.	
Packaging	Adhesive strength shall be tested by ASTM F-88 to be not less than 3N	
Nucleated Cell Count	Nucleated cells should have more than $3.86x10^5$ per ml of adipose tissue	
Nucleated Cell Viability	Viability of nucleated cells should be more than 71.4%	
Extraction test		
Appearance	When observe sample preparation extract with naked eyes, there should not be foreign material.	Pass
pH	Difference in pH S: 1.5	
KMn04 Reducing agents	Difference in titres S: 2.0 ml	
Evaporating residue	Difference in extractables S 1.0 mg	
Heavy metal (as Pb)	Not darker than standard solution.	
UV-vis Spectrum	Difference in absorbance (250nm – 350nm) S:0.1	

2) Biocompatibility

#	Test item	Test method / Test criteria	Test result
1	Cytotoxicity	ISO 10993-5 Tests for in vitro cytotoxicity	Pass
2	Skin Sensitization Test	ISO 10993-10 irritation and skin sensitization	Pass
3	Intracutaneous Reactivity Test	ISO 10993-10 Test for irritation and skin sensitization, maximization test for delayed hypersensitivity	Pass
4	Acute Systemic Toxicity Test	ISO 10993-11 Test for systemic toxicity -Acute Systemic Toxicity	Pass
5	Pyrogen Test	ISO 10993-11 Tests for systemic toxicity, Annex(F) Information on material-mediated pyrogens.	Pass
6	Hemolysis Test	ISO 10993-4 Selection of tests for interactions with blood	Pass

The performance tests demonstrated that Automatic Tissue Processing Unit performs in a substantially equivalent manner to the predicate device.

7. Comparison Table of ACPU-100/ACPU-200

Manufacturer	BSL Co.	AdiprepTM	Remark
SIO(K) No.		K121005	N/A
Indication for use	The Automatic Tissue Processing Unit is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. The Automatic Tissue Processing Unit is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system.The Automatic Tissue Processing Unit 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 * aparoscopic Surgery * Arthroscopic Surgery	The AdiPrep™ Adipose Transfer System isused in medical procedures involving the harvesting and transferring of autologous adipose tissue. The Adiprep system is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system. AdiPrep™ Adipose Transfer system is intended for use inthe following surgical specialties when the concentration of harvested adipose tissue is desired. * Neurosurgery * Gastrointestinal Surgery * Urological Surgery * Plastic and Reconstructive Surgery * Generalsurgery * Orthopedic Surgery * Gynecological Surgery * Thoracic Surgery * Laparoscopic Surgery * Arthroscopic Surgery	Same
Model/type	ACPU-100/ACPU-200	ADI-25-01 AdiPrep Procedure pack	N/A
Appearance			Different
Processing Pack:Materials	ACPU-100 kit / ACPU-200 kit	Components - Syringes with removable plunger, centrifuge tubes with filter, aspiration & fat injection cannula,fat injection syringes, skin puncture needles,and oil extraction syringe & needle. Cannula & syringes composed of medicalgrade plastics.	Different
Fill volumes	5 to 25ml	5 to 25ml	same
Sterilization Method	Ethylene-OxideGas(EtO)	Ethylene-Oxide Gas (EtO)	same
Autologous Adipose Product			
Nucleated cell count (x10^5 ml of product)	3 86 over	Mean 1.848	Similar
Nucleated cell viability	71.4% over	Mean 83.5	Similar
Processing capabilities			
Volume	5 to SOml	Sta 25ml	Similar

Low-g-force	Centrifuge to spin for approximately 4 minutes at 1250 g-force (ACPU-200 kit) Centrifuge to spin for approximately 5 minutes at 375 g-force (ACPU-100 kit)	Centrifuge to spin for approximately 4 minutes at 1250 g-force	Same and different
Laboratory centrifuge	ACS Combo-A Centrifuge CENTRIFUGES (MICRO, ULTRA, REFRIGERATED) FOR CLINICAL USE or laboratory centrifuge for clinical use	SmartPReP2 centrifuge is a general-purpose laboratory centrifuge for clinical use	N/A

Conclusion

The device is investigated for function and effectiveness to compare the operation of function between proposed device and predicate device (K121005). Comparison results demonstrate that the specifications and performance of the device are same as functional and effective as the legally marketed predicate device. Therefore, it is concluded that is Automatic Tissue Processing Unit of BSL Co. substantially equivalent to the legally marketed predicate device.