February 9, 2023



BSL Co. 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 <a href="http://www.fda.gov/">http://www.fda.gov/</a> MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandList ing/ucm053185.htm</a>

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 <a href="https://www.federalregister.gov/documents/2021/09/13/2021-18912/consolidation-of-devices-that-process-autologous-human-cells-tissues-and-cellular-and-tissue-based">https://www.federalregister.gov/documents/2021/09/13/2021-18912/consolidation-of-devices-that-process-autologous-human-cells-tissues-and-cellular-and-tissue-based</a>).

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 <u>Julia.Russell@fda.hhs.gov</u>.

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);

# Page 2 Mr. Peter Chung

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 <u>http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</u> 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

# Indications for Use

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 CER 801 Subpart D)	Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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* 

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#### 510(k)Summary [as required by 807.92(c)]

#### 1Applicant

- 1) Company: BSLCo.
- 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
- Panel: General and Plastic surgery
- 3. The legally marketed device to which we are claiming equivalence K121005, AdiPrep<sup>™</sup>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
Annearance	Itshould not be defects inflaws, breakage or contamination of	
Appearance	foreign objects.	
	When measuring with Vernier calipers, according to the	
Measurement	dimension of 'shape and structure' part, the stated should be	
	within $\pm 5$ %.	
Leakage	When tested according to the test method, there should be no	
Leakaye	leakage.	
Residuals of cleaning liquid	When tested accordingto the test method, the residuals of	Pass
Residuals of cleaning liquid	cleaning liquid should be less than 20 ml.	
Packaging	Adhesive strength shall be tested by ASTM F-88 to be not less	
Fackaging	than 3N	
Nucleated Cell Count	Nucleated cells should have more than 3.86x10 <sup>5</sup> per ml of	
Nucleated Och Obdit	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,	
Appearance	there should not be foreign material.	
рН	Difference in pH S: 15	
KMn04 Reducing agents Difference intitres S: 2.0 ml		Pass
Evaporating residue Difference in extractables S 1.0 mg		
Heavy metal (as Pb) Not darker than standard solution.		
UV-vis Spectrum	Difference inabsorbance (250nm-350nm) S:0.1	

#### 2 Biocompatibility

#	Testitem	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 10993-11Tests 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 ina substantially equivalent manner to the predicate device.

SIQ(K) No.      K121005      N/A        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 market diposet system. The Automatic Tissue Processing Unit is intended for use in the following surgical specialities when the concentration of harvested adipose tissue is intended for use in the following surgical specialities when the concentration of harvested adipose tissue is desired.      The Automatic Tissue Processing Unit is intended for use in the following surgical specialities when the concentration of harvested adipose tissue is desired.      Same        Indication for use      desired      The Romatic Tissue Processing Unit is intended for use in the following surgical specialities when the concentration of harvested adipose tissue is desired.      Same        Indication for use      desired      The Automatic Tissue Processing Unit is used for use in the following surgical specialities when the concentrating adipose tissue is desired.      Same        Indication for use      desired      The Automatic Tissue Processing Unit is used for use in the following surgical specialities when the concentrating adipose tissue is desired.      Same        Indication for use of the Reconstructive Surgery      General surgery      General surgery      Same        Modelitype      ACPU-t00 Kit/ACPU-200      ADI-25-01Adi Prep Procedure pack      N/A        Processing Pack.Matoriab	Manufacturer	BSL Co.	AdiprepTM	Remark
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*Arthroscopic Surgery*Arthroscopic SurgeryN/AModel/typeACPU-100/ACPU-200ADI-25-01 AdiPrep Procedure packN/AAppearanceImage: Components - Syringes with removable plunger, centrifuge tubes with filter, aspiration & fat injection syringes, skin puncture needles, and oil extraction syringe kneedle. Cannula & syringes composed of medicalgrade plastics.DifferenFill volumes5 to 25ml5 to 25mlSameAutologous Adipose ProductEthylene-Oxide Gas (EtO)SimilarNucleated cell count (x10' ml of product)71.4% overMean 83.5SimilarProcessing Pack:Materials71.4% overSta 25mlSimilar		* aparoscopic Surgery	* Laparoscopic Surgery	
Model/type      ACPU-100/ACPU-200      ADI-25-01AdiPrep Procedure pack      N/A        Appearance      Image: Compose of the second s		*Arthroscopic Surgery	* Arthroscopic Surgery	
Appearance    Image: Components - Syringes with removable plunger, centrifyinge tubes with filer, aspiration & fait injection cannula, fait injection syringes, skin puncture needles, and oil extraction syringes, needle. Cannula & syringes composed of medicalgrade plastics.    Different Sterilization & Sto 25ml    Different & Sterilization & Sto 25ml    Ste 25ml    Sterilization & Sto 25ml	Model/type	ACPU-100/ACPU·200	ADI-25-01AdiPrep Procedure pack	N/A
Processing Pack:MaterialsACPU-100 kit/ACPU-200 kitComponents - 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 plifferentFill volumes5 to 25ml5 to 25mlsameSterilization MethodEthylene-OxideGas (EtO)Ethylene-Oxide Gas (EtO)sameAutologous Adipose Product0Ethylene-Oxide Gas (EtO)sameNucleated cell count (x105 ml of product)3 86 overMean 1.848SimilarNucleated cell viability71.4% overMean 83.5SimilarProcessing capabilities5 to SOmlSta 25mlSimilar	Appearance			Different
Fill volumes  5 to 25ml  5 to 25ml  same    Sterilization Method  Ethylene-OxideGas(EtO)  Ethylene-Oxide Gas (EtO)  same    Autologous Adipose  Product  same  same    Nucleated cell count (x10 <sup>5</sup> ml of product)  3 86 over  Mean 1.848  Similar    Nucleated cell viability  71.4% over  Mean 83.5  Similar    Processing capabilities  5 to SOml  Sta 25ml  Similar	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
Sterilization Method  Ethylene-Oxide Gas (EtO)  Ethylene-Oxide Gas (EtO)  same    Autologous Adipose Product	Fill volumes	5 to 25ml	5 to 25ml	same
Method  Etnylene-Oxide Gas (EtO)  Etnylene-Oxide Gas (EtO)  same    Autologous Adipose Product	Sterilization			0.0770
Autologous Adipose Product    Nucleated cell    count (x10 <sup>5</sup> ml    of product)    Nucleated cell    viability    71.4% over    Mean 83.5    Similar    Processing capabilities    Volume  5 to SOml    Sta 25ml	Method	Ethylene-OxideGas(EtO)	Etnyiene-Oxide Gas (EtO)	same
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Volume 5 to SOmI Sta 25ml Similar	Processing capa	bilities		

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

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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 isa 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.