U.S. FOOD & DRUG ADMINISTRATION

BSL Co., Ltd
Attention: James W. Monroe
Global RQC Med Device Solutions, LLC.
319 Shilling Dr.
Somerset, NJ 08873

February 9, 2023

Re: BK220722 (Formally K202443)
Trade/Device Name: Smart Kit Basic, Smart Kit Pro
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Mr. Monroe:

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 11, 2021. 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

March 11, 2021

BSL Co., Ltd
% James Monroe
President & CEO
Global RQC Med Device Solutions, LLC.
319 Shilling Dr.
Somerset, New Jersey 08873

Re: K202443
Trade/Device Name: Smart Kit Basic, Smart Kit Pro
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: February 3, 2021
Received: February 5, 2021

Dear James Monroe:

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,

Cindy Chowdhury, Ph.D., M.B.A.
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)*
K202443

Device Name

Smart Kit

Indications for Use *(Describe)*

The Smart Kit is disposable and is indicated for autologous fat transfer. The autologous fat transfer is also technically called as autologous fat grafting or reinjection of concentrated adipose-tissue into the recipient body areas. The Smart kit can be used for concentration and transfer of homogenous adipose tissues with legally marketed lipoplasty system when the concentrated and homogenous fat tissue is re-injected into the recipient body areas of the same patient autologously.

This device is intended for autologous fat transfer. The Smart Kit is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired.

Neurosurgery / Gastrointestinal Surgery / Urological Surgery / General surgery / Orthopedic Surgery / Gynecological Surgery / Thoracic Surgery / Laparoscopic Surgery / Arthroscopic Surgery / Plastic and reconstructive 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.

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Department of Health and Human Services
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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

Date of Preparation: February 10, 2021

Submitter: Jun Seok Lee, President
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Trade/Device Name:	Smart Kit
Common/Usual Name:	Suction lipoplasty system
Classification Name:	System, Suction, Lipoplasty
Regulation Number:	21 CFR Part 878.5040
Regulation Name:	General & Plastic Surgery
Regulatory Class:	Class II
Product Code:	MUU
Predicate Device:	Dermapose Refresh (K193363, clearance received April 14,2020)

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 and etc. In addition, the harvested fat tissues are not homogeneous and contain bigger fibrotic tissues. Smart kit is designed and developed for harvest of a variety of sizes of homogeneous adipose tissues in a closed sterile way for autologous fat transfer surgical technique.

Using a separate cannula, Manual handheld suction unit, and plunger, aspirate the adipose tissue or fill the syringe with adipose tissue and centrifuge with the cap in front of the syringe. Centrifuged adipose tissue is divided into blood and fluid layer, adipose tissue layer, and free oil layer. Those are located at the bottom of the piston. After centrifugation, the plunger is pushed unlocked to the piston and free oil is drained to the outside of the syringe as the free oil moves to the top of the piston through the hole at the front of the piston. Open the cap in front of the syringe, lock the plunger completely and push it, the blood and fluid layers at the bottom of the adipose tissue will be drained and only the adipose tissue will remain inside the syringe. Depending on the syringe capacity, there are three types of piston: 10ml, 20ml, 60ml. The built-in filter adapter consists of a filter for separating the fiber and adipose tissue to facilitate movement through needles of lumpy adipose tissues and a body for receiving it.

Connect the syringe containing the adipose tissue and the empty syringe to the connection parts at both ends of the built-in filter adapter and push the plunger of the syringe containing the adipose tissue to allow the adipose tissue to pass through the filter. Fiber and adipose tissues larger than the pore size is filtered, and adipose tissue smaller than the pore size of the filter is passed through to separate adipose tissue.

Smart Syringe:

Filter piston syringe is equipped with a piston built-in filter. After the filter piston syringe is filled with aspirated adipose tissue, filter piston syringe capped with a syringe CAP, centrifuged and divided into blood and fluid layers, adipose tissue layer, and free oil layer due to differences in specific gravity. During the centrifugation process, the weight valve in the piston operates to open the oil-passage, and the free oil passes through the filter of the piston. The adipose tissue that is larger than the pore of the filter can not pass through, so it stays between the front of the filter piston and the blood & fluid layer. The Adipose tissue and free oil are separated. After the centrifugation is completed, push the piston built-in filter

through the filter piston plunger to remove blood and fluid layer, leaving only adipose tissue in the device.

Smart Lock

A separate handheld suction unit that is reusable.

Syringe Connector

Luer to Luer connector between two syringes for fat transfer, that is disposable

Syringe Handle

Assist in fat processing, disposable

Adinizer

Concentrates adipose-tissue passes through (4000-400 μm) mesh outlet into the reconstructing area.

Smart Kit (System) – The device comes is available either as a) Smart Kit Basic, b) Smart Kit Pro

1. Smart Kit Basic:
    a. Piston
    b. Plunger
    c. Syringe CAP
    d. Syringe Handle
    e. Syringe Connector
    f. Smart Syringe

2. Smart Kit Pro:
    g. Piston
    h. Plunger
    i. Syringe CAP
    j. Syringe Handle
    k. Syringe Connector
    l. Smart Syringe
    m. Adinizer (Mesh Filter)

Smart kit is recommended to be used by the well-trained physicians for liposuction and fat transfer technique. This device is sterile and for single-use only.

Intended Use/Indications for Use:

The Smart Kit is disposable and is indicated for autologous fat transfer. The autologous fat transfer is also technically called as autologous fat grafting or reinjection of concentrated adipose-tissue into the recipient body areas. The Smart kit can be used for concentration and transfer of homogenous adipose tissues with legally marketed lipoplasty system when the concentrated and homogenous fat tissue is re-injected into the recipient body areas of the same patient autologously.

This device is intended for autologous fat transfer. The Smart Kit is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired.

Neurosurgery / Gastrointestinal Surgery / Urological Surgery / General surgery / Orthopedic Surgery / Gynecological Surgery / Thoracic Surgery / Laparoscopic/ Arthroscopic Surgery/Plastic and reconstructive surgery.

Summary of Technology Characteristics:
Smart Kit is substantially equivalent to the predicate device. A comparison of technological characteristics is provided in the table below. Both the subject device and the predicate device provide a method of harvesting, concentrating, and transferring of autologous adipose tissue. In addition, both the subject and predicate devices are pre-assembled systems which are provided sterile (via ethylene oxide) and intended for single use.

Attribute	Subject Device Smart Kit	Predicate Dermapose™ Refresh (K193363)	Same/Different
Device Classification	System, Suction, Lipoplasty	System, Suction, Lipoplasty	
Regulation Number	21CFR 878.5040	21 CFR 878.5040	
Product Code	MUU	MUU	
Intended Use	The Smart Kit is disposable and is indicated for autologous fat transfer. The autologous fat transfer is also technically called as autologous fat grafting or reinjection of concentrated adipose-tissue into the recipient body areas. The Smart kit can be used for concentration and transfer of homogenous adipose tissues with legally marketed lipoplasty system when the concentrated and homogenous fat tissue is re-injected into the recipient body areas of the same patient autologously. This device is intended for autologous fat transfer. The	The Dermapose™ Refresh 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	

Attribute	Subject Device Smart Kit	Predicate Dermapose™ Refresh (K193363)	Same/Different
	Smart Kit is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired. Neurosurgery / Gastrointestinal Surgery / Urological Surgery / General surgery / Orthopedic Surgery / Gynecological Surgery / Thoracic Surgery / Laparoscopic Surgery / Arthroscopic Surgery / Plastic and reconstructive surgery	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 reimplanted, the harvested fat is only to be used without any additional manipulation	
Technological Characteristics (Components)	Smart Kit is composed of 4 major parts: 1. Harvester (Piston, plunger, syringe cap, luer to luer syringe connector, filter piston syringe(Smart syringe) need to remove piston plunger,2. Builtin filter adaptor(Adinizers), 3. Syringe handle 4. Manual handheld suction unit (Smart Lock) **Smart Kit Variations:** 1. **Smart Kit Basic**(SKT-010,SKT-020, SKT-060, SKT- 011, SKT-021, SKT-061) a. Smart Lock (PLK-002, PLK-003) b. Smart Syringe (SKT-SS-100) 2. **Smart Kit Pro**(SKT-14060,SKT-24060, SKT-12440, SKT-22440, SKT-12460, SKT-22460) a. **Adinizer** (SKT- AN-100, SKT-AN-200, SKT- AN-400, SKT-AN-600, SKT- AN-1200, SKT-AN-2400,SKT-AN-4000, SKT-AN-4060, SKT-AN-4040, SKT-	• 50 mL polycarbonate harvesting and processing syringe unit with vacuum lock and 30 mL output syringe containing a two- stage sieve filter on the inlet • Two 30 mL polypropylene luer-lock syringes • Three luer caps • Luer-to-luer adapter	

Attribute	Subject Device Smart Kit	Predicate Dermapose™ Refresh (K193363)	Same/Different
	AN-2440, SKT-AN-101, SKT-AN-201, SKT-AN-401, SKT-AN-601, SKT-AN-1201, SKT-AN-2401, SKT-AN-4001, SKT-AN-2460, SKT-AN-1240, SKT-AN-6020, SKT-AN-24201, SKT-AN-40201) b. **Smart Syringe** (SKT-SS-100)		
Device Size	• BD syringe 10cc (NB No.0086) • BD syringe 20cc (NB No.0050) • BD syringe 60cc (NB No.0050)	50 ml syringe	
User Environment	Physician	Physician	
Method of Harvesting	Cannula	Cannula	
Construction	Preassembled	Preassembled	
Device Performs Harvesting	Syringe generated vacuum-lock	Syringe generated vacuum-lock	
Filter/Mesh	Concentrated adipose-tissue passes through (4000-400 μm) mesh outlet into the reconstructing area.	1000 and 800 micron mesh at outlet – collected adipose tissue passes though both	
Sterilization Method	Ethylene-Oxide Gas (EtO)	Ethylene-Oxide Gas (EtO)	
Sterility Assurance Level	SAL 10^{-6} Shelf life: 3 years	SAL 10^{-6} Shelf life: 3 years	
Disposable or reusable	Single Use, Disposable	Single Use, Disposable	
Biocompatibility	Biocompatible	Biocompatibility	

Performance Testing:
Smart Kit was tested in accordance with established protocols and met the acceptance criteria for all tests performed.

Performance testing include:

Test Item	Test Requirement
Appearance	There should be no visible scratches, damage, or foreign material
Measurement	When measuring with Vernier calipers, according to the dimension of ‘‘shape and structure’’ part, the stated should be within ±5%
Water Tightness	When tested according to the test method, there should be no leakage
Centrifugation Compatibility Test (Leakage)	When tested according to the test method, it should be aspirated to the maximum capacity without leakage
Cell Viability Test	The finally filtered adipose tissues for autologous fat transfer should maintain at least over 85 % of the cell viability.
Pore Size	When measuring with Vernier calipers, according to the dimension of ‘shape and structure’ part, the stated should be within ±15 %.
pH	Difference of pH ≤1.5
Potassium permanganate reducing substances	Difference of the consumption ≤ 2.0 mL
Evaporating residue	Difference of residues ≤ 1.0mg
Heavy Metals	The test solution should not be darker than blank solution.
Ultraviolet-visible	Difference of the maximum absorbance at (250~350) nm ≤0.1

Sterilization and Shelf Life

Smart Kit was verified for validation for 3 years (36 months) by testing physicochemical changes and packaging of the materials and the product before, middle, and after acceleration aging according to ISO 11607.

Sterilization was conducted on the Smart Kit Fat Separator with Ethylene oxide gas.

Sterilization is performed with the cycle validation on the report in accordance with EN ISO11135:2014 Sterilization of medical devices validation and routine control of sterilization by Ethylene oxide gas. The sterilizing cycle has been validated to ensure our products to be sterilized to an S.A.L. of at least 10^{-6} by EN ISO11135:2014 by the method of over-kill.

Biocompatibility

Biocompatibility testing for Smart Kit was performed in accordance with the requirements of ISO 10993-1:2009 for external communicating devices having contact < 24 hours. In all instances, the test articles were found to be biocompatible. The following tests were conducted:

- Hemocompatibility, per ISO 10993-4:2017
- Cytotoxicity, per ISO-10993-5: 2009
- Sensitization, Intracutaneous Reactivity, per ISO 10993-10: 2010
- Acute Systemic Toxicity, Pyrogen per ISO 10993-11:2018

Statement of Substantial Equivalence

Based on the information contained in this submission, it is concluded that the Smart Kit is substantially equivalent to the predicate device, Dermapose Refresh. Smart Kit has the same indications for use, as well as similar technological characteristics and principles of operation as its predicate device. Thus, Smart Kit is substantially equivalent to the Dermapose Refresh (K193363).