August 07, 2024

LHbiomed Co., Ltd.
℅ Peter Chung
President
Plus Global
300, Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K212969
Trade/Device Name: Liposaver
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: October 31, 2023
Received: October 31, 2023

Dear Peter 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.08.07 11:21:24 -04'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
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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)*
K212969

Device Name
LipoSaver™

Indications for Use *(Describe)*
LipoSaver™ is intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring. LipoSaver™ is indicated for use in the following surgical specialists when the fragmentation and aspiration of soft tissue is desired:
- Plastic and Reconstruction Surgery
- Orthopedic 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.

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510(k) Summary

K212969

1. Applicant

Company : LHbiomed Co., Ltd.
Address : #806, Medical device Complex Center, 200, Gieopdosi-ro, Jijeong-myeon, Wonju-si, Gangwon-do, Republic of Korea
Tel : +82-33-901-0411
Fax : +82-33-901-0422
Contact person : Peter Chung, 412-512-8802
Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
Date Prepared: July 12, 2024

2. Device Information

Trade Name : LipoSaver™
Common Name : Suction lipoplasty system
Classification Name : System, Suction, Lipoplasty
Product Code : MUU
Regulation Number: 21 CFR 878.5040
Class of device: Class II
Panel : General & Plastic Surgery
Model name: LS-1000, LS-2000

3. Predicate Device

The legally marketed device to which we are claiming equivalence
: K190551, VASERlipo System
Classification System, Suction, Lipoplasty
Product Code: MUU
Regulation Number: 21 CFR 878.5040
Class of device: II

4. Device description :

LS-1000/LS-2000 is an ultrasonic surgical unit which uses ultrasound frequency vibration to fragment, emulsify subcutaneous fatty tissues.
The PZT ceramic crystals in handpiece of LS-1000/LS-2000 transforms electrical signal into ultrasonic vibrations, and these vibrations transmit to the probe of LS-1000/LS-2000 which performs the function of fragmenting and emulsifying the subcutaneous fatty tissues.
The LS-1000/LS-2000 is able to adjust the operating features such as vibration amplitude and frequency, and provides two modes as follows:
- N mode (continuous mode)
- Z mode (pulsed mode)

5. Indication for Use:

LipoSaver™ is intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring. LipoSaver™ is indicated for use in the following surgical specialists when the fragmentation and aspiration of soft tissue is desired:
- Plastic and Reconstruction Surgery

6. Technological characteristics

The technological characteristics of the LipoSaver are below:

Characteristic	K212969
Electrical shock	Class I, Type BF
Operating Frequency	35kHz~40kHz
Cannula	Ø3.7, 330mm Ø2.9, 315mm Ø1.9, 121mm

7.Comparison of technological characteristics with the predicate device

K190551, VASERlipo System

The comparison of features and operation principles between LipoSaver™, Suction lipoplasty system from LHbiomed Co., Ltd., VASERlipo System, Suction lipoplasty system from Solta Medical is listed as follows:

Proprietary	Subject Device	Predicate Device VASERlipo System	Substantially Equivalent or Not Substantially Equivalent
510(k) Number	K212969	K190551	N/A
Common Name	Suction lipoplasty system	Suction lipoplasty system	Substantially Equivalent
Trade name	LipoSaver™	VASERlipo System	N/A
Manufacturer	LHbiomed Co., Ltd.	Solta Medical	N/A
Product Classification	II	II	Identical
Protection degree and type for electrical shock	Class I, Type BF	Class I, Type BF	Identical
Operating Frequency	35kHz~40kHz	36kHz Nominal	Similar
Cannula	Ø3.7, 330mm Ø2.9, 315mm Ø1.9, 121mm	1~6mm diameter 7~40cm length	Similar
Performance Data: Safety and Performance			
Performance	Proposed device	Predicate Device K190551	Substantially Equivalent or Not Substantially Equivalent
Biocompatibility	Conformed to ISO 10993-1, ISO10993-5, ISO10993-10, and ISO 10993-11	Conformed to ISO 10993-1, ISO 10993-5, ISO 10993-10, and ISO 10993-11	Identical
Electrical Safety	Conformed to IEC 60601-1	Conformed to IEC 60601-1	Identical
Electromagnetic Compatibility	Conformed to IEC 60601-1	Conformed to IEC 60601-1	Identical

Comparison Table for IFU Statements

	Subject Device (K212969)	**Predicate Device (K190551)**
Indication for Use	LipoSaver™ is intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring. LipoSaver™ is indicated for use in the following surgical specialists when the fragmentation and aspiration of	The VASERlipo System is intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring. The VentX console is intended for the suction or aspiration of fluids and tissue during surgical procedures. The VentX console is designed to operate with

	soft tissue is desired: - Plastic and Reconstruction Surgery - Orthopedic Surgery	the VASERlipo System or as a stand-alone system. The VASERlipo System is intended for the fragmentation, emulsification and aspiration of subcutaneous fatty tissue for the purpose of aesthetic body contouring. The VASERlipo System is also indicated for use in the following surgical specialties for the fragmentation, emulsification and aspiration of soft tissues: • Neurosurgery • Gastrointestinal and affiliated organ surgery • Urological surgery • Plastic and reconstructive surgery • General surgery • Orthopedic surgery • Gynecological surgery • Thoracic surgery and • Laparoscopic surgery
Key Differences between K212969 and K190551		
Primary Function	Fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring.	Fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring.
Indicated Surgeries	• Plastic and reconstructive surgery • Orthopedic surgery	• Neurosurgery • Gastrointestinal and affiliated organ surgery • Urological surgery • Plastic and reconstructive surgery • General surgery • Orthopedic surgery • Gynecological surgery • Thoracic surgery and • Laparoscopic surgery
Additional Functionality of K190551	N/A	• The VentX console, part of the VASERlipo System, is intended for the suction or aspiration of fluids and tissue during surgical procedures. • The VentX console can operate with the VASERlipo System or as a stand-alone system.

∴ In summary, while the VASERlipo system has a wider range of applications, both devices are intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring, making the two devices substantially equivalent.

Substantial equivalence summary

The review of the indications for use and technical characteristics provided demonstrates the LipoSaver™ is substantially equivalent to the predicate device.

8. Brief Summary of Nonclinical Tests and Results

Safety tests of the LipoSaver™ have demonstrated its compliance with applicable requirements of the following electrical standards:

No.	Test item	Test Standard
Biocompatibility test		
1	Cytotoxicity test	ISO 10993-5
2	Intracutaneous reactivity test	ISO 10993-10
3	Skin sensitization test	ISO 10993-10
4	Acute Systemic Toxicity test	ISO 10993-11
5	Pyrogenicity	USP 43 <151>
Electrical safety test		
1	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance	IEC-60601-1
2	EMC Test	EN 60601-1-2

No.	Test item	Result
1	IEC 60601-1:2005/AMD2:2020	Pass
2	Output acoustic power	0~40W Max±20%

9. Conclusion:

The LipoSaver™ shares the same indications for use, design features, and functional features, and thus is substantially equivalent to the predicate device. Non-clinical test results demonstrate that the LipoSaver™ is substantially equivalent to the predicate device and no new issues of safety or effectiveness have been raised.