DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 30, 2017

Baisheng Medical Co., Ltd.
% Mr. Albert T.W. Li
Manager, Principle Administrator
Office of Medical Device Evaluation
Center for Measurement Standards
Industrial Technology Research Institute
Room 307, Bldg. 4, 321, Sec. 2 Kuang Fu Rd
Hsinchu, Taiwan 30011 R.O.C.

Re: K162034
Trade/Device Name: OBS Electrosurgical Generator (model: OBS-350A)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 22, 2016
Received: July 22, 2016

Dear Mr. Li:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162034

Device Name
OBS Electrosurgical Generator

Indications for Use *(Describe)*
The Electrosurgical Generator (OBS-350A) is a non-sterile, reusable multi-purpose electrosurgical generator that is designed to perform monopolar and bipolar functions in the surgical operation area.

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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PREMARKET NOTIFICATION
510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and Title 21 CFR §807.92.

The assigned 510(k) Number: K162034

1.0 Sponsor Identification

Baisheng Medical Co.,Ltd.

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Fax:	+86-750-6616122
General manager:	Mr Chen xi
E-mail:	renzheng@bs0750.com
Contact person:	Peter
E-mail:	peter@bs0750.com
Date	Mar 27th, 2015

2.0 Proposed Device Identification

Trade Name: OBS Electrosurgical Generator
Model: OBS-350A
Common Name: Electrosurgical Generator

Regulatory Information:
Classification Name: electrosurgical, cutting & coagulation & Devices and accessories;
Classification: Class II(Product Code GEI)
Regulation Number: 21CFR 878.4400
Review Panel: General& Plastic Surgery

3.0 Predicate Device Identification:

510(k) Number: K944602

Predicate Device Trade name: Valleylab Force FX

Manufacturer Name: VALLEYLAB INC.

Address: 5920 LONGBOW DRIVE BOULDER, CO 80301

4.0 Indication for use

The Electrosurgical Generator (OBS-350A) is a non-sterile, reusable multi-purpose electrosurgical generator that is designed to perform monopolar and bipolar functions in the surgical operation area.

5.0 Device Description

5.1 Operation modes and functions

- **3 CUT modes:**

Pure CUT: Pure be used for a clean, precise cut in any tissue with little or no hemostasis.

Blend 1: be applied to any tissues and make slight hemostasis effect while cutting.

Blend 2: be applied to any tissues and make good hemostasis effect while cutting.

- **3 Coagulation (COAG) modes**

COAG1 (Spray): Spray for coagulating large tissue areas with superficial depth of necrosis.

COAG2 (F**orced)**: can be used in laparoscope surgery and swift contacting coagulation of other elaborate tissues.

COAG3 (Soft): Its coagulation effect on the tissues is deep, but the scope is rather small because of its good effect on the single blood spot.

- **2 Bipolar modes**

Bipolar1 (Macro): be used for rapid coagulation such as artery vessel sealing, the voltage is higher and there is more power than the other bipolar mode.

Bipolar2 (Micro): be used for most bipolar applications, voltage is kept low to prevent sparking, the power remains constant over a specific range of tissue resistance, allowing consistent tissue effect.

5.2 Physical Characteristics:

The generator is enclosed in a metal and molded plastic enclosure and will have an angled front panel in the display and controls area. The front panel displays and controls will be sealed to facilitate cleaning and minimize the possibility of problems caused by accidental spills. The receptacles for the active electrosurgical accessories will be in a recessed area and will conform to IEC60601-1:2005/(R) 2012 And A1:2012.

5.3 Device components

Chassis and Cover, Front panel controls, Power supply board, Microprocessor board, Footswitch board, Interface circuits, Front panel receptacles.

5.4 Accessories compatible

- First, the accessories shall be Legally marketed in America;
- Second, Compatibility data: max electrical capacity of these accessories ⩾4500 Vp which will be available.
  - ✓ Electrosurgical pencil
  - ✓ Split Electrosurgical pad (also named neutral electrode, return electrode, neutral pad…)
  - ✓ Electrosurgical bipolar forceps
  - ✓ Footswitch for Monopolar procedures
  - ✓ Footswitch for Bipolar procedures
  - ✓ Cord for bipolar forceps
  - ✓ Cord for electrosurgical pad

Note: The proposed device in this submission is only the ESU generator submitted.

To avoid incompatibility and unsafe operation, we recommend using the following OBS accessories with the OBS-350A:

- ✓ Electrosurgical pencil (510(k) No.: K092634)
  OBS-Db(#0039D, #0039H, #0025D, #0035H)
  OBS-Dr(#0038D, #0038H, #0030D, #0030H)
  OBS-Df(#0048D, #0048H, #0040D, #0040H)
- ✓ Split Electrosurgical pad (510(k) No.:K102372)
  GBS-Db(#1031a, #1131a, #1031b, #1131b, #1041a, #1141a, #1031n, #1131n, #2031, #2131, #3031, #1031ac, #1041ac)

5.5 Special features

- Three CUT modes: Pure CUT, Blend 1, Blend 2;
- Three COAG mode: COAG1(Spray), COAG2(Forced), COAG3(Soft);
- Two Bipolar modes: Bipolar1(Macro) and Bipolar2(Micro);
- Memory: 10 memory Presets, the unit automatically reset to the last activated Preset setting;

- CQMS (contact quality monitoring system): The ESU pad contact quality monitor system (CQMS) will measure the resistance bewteen the ESU pad and patient, if the resistance was beyond the defined upper limit, the alarm system will be activaed.

  During **monopolar** electrosurgery, a patient **Split** ESU pad is always required to safely recover the current that flows through the patient's body and return it to the generator. A reduction in surface area contact or poor conductivity between the patient and the ESU pad can cause the current to become concentrated, potentially resulting in burns at the ESU pad site.

  The OBS-350A generator uses the CQMS to monitor the quality of electrical contact between the patient ESU pad and the patient. The CQMS function is designed to minimize the risk of burns at the ESU site due to a reduction in patient contact area during monopolar electrosurgery.
- How the CQMS works

  The CQMS continuously measures the resistance at the ESU pad site and compares it to a standard value of safe resistance (less than 113ohms), thus under the condition of ESU pad releases or shrinks, the contact area to skin would be reduced, and the contact resistance increased, when the resistance is above 113ohms, the alarm will be activated by Red of "ALARM" indicator as well as Error code(Err--0) displayed on the CUT screen, at the same time a continuous alarm voice(> 65db) initiated, and the generator will stop output simultaneously, the alarm cannot be disabled unless the ESU pad adhered in a good condition again.
- Power ON self diagnostics: In the self diagnosis process after Power ON, all working modes and functions operating are simulated and monitored by software control to determine whether they are performed normally, followed by transmitting of corresponding test data to the display module through the control module. If failure occurs, the respective code will be displayed accordingly as prompt and alarm voice delivered simultaneously, which disables all subsequent operations automatically.
- PPS (peak power system):The OBS-350A automatically senses resistance and adjusts the output voltage to maintain a consistent effect across different tissue density. This adjustment is based on the selected mode, the power setting and the level of tissue resistance. The maximum output voltage is controlled to reduce capacitive coupling and video interference and to minimize sparking.
  - Pure CUT, Blend CUT and Bipolar modes are equipped this PPS function.

5.6 Duty Cycle

Under maximum power settings and rated load conditions (pure cut350W, 500ohm load) the generator is suitable for activation times of 10seconds on, 30seconds off for 1 hour.

6.0 Performance Data

The performance data were provided in support of the substantial equivalence determination. All standards applied were FDA recognized international standards. The software validation activities were performed in accordance with the FDA Guidance, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” (May 11, 2005). The device software is considered a “Moderate Level of Concern”.

6.1 Performance Testing – Bench

In general, the evaluations compared the function of the OBS-350A against the performance characteristics defined by the Design Specification and in comparison to the performance characteristics of the predicate devices. To demonstrate substantial equivalence the following aspects were considered within the validation versus the predicate devices. The results demonstrate that comparable tissue effects and electrical waveforms are achieved with subject and predicate devices for all modes of operation.

The purpose of the bench validation testing was to show equivalence of the electrical waveform between the subject and predicate devices. An oscilloscope and high voltage probe were used as measuring and test equipment. The electrical waveforms of the OBS-350A were comparable to the electrical waveforms of the predicate devices. This was confirmed for all output modes (waveforms) at rated load.

The tissue thermal effects test was conducted by OBS-350A and predicate devices to demonstrate the tissue thermal effects equivalence in porcine muscle, kidney and liver tissue. Thermal Zone Damage Report for OBS-350A and predicate devices are provided in Chapter 029_Appendix 8.

Comprehensive validation bench tests demonstrated and confirmed substantial equivalence to the predicate devices. Testing confirmed that comparable tissue effects and electrical waveforms could be achieved for all modes of operation. Clinical and animal studies were not deemed necessary to support substantial equivalence.

7.0 Substantially Equivalent (SE) Conclusion

The following table compares the proposed device with the predicate device on respects of intended use, technological characteristics and principles of operation as well as performance conformance.

Items	Proposed device OBS-350A	Predicate device (Force FX)	SE Compare
Product Code	GEI	GEI	Same
Regulation Number	878.4400	878.4400	Same
Indication for use	The Electrosurgical Generator (OBS-350A) is a non-sterile, reusable multi-purpose electrosurgical generator that is designed to perform monopolar and bipolar functions in the surgical operation area.	The Valleylab Force Fx is an isolated, microprocessor based ESU generator intended for use in the operating room for general procedures where ESU cutting and coagulation is required. The generator is equipped with monopolar and bipolar outputs.	SE
Energy	HF energy	HF energy	Same
Input power	120V/230V, 60Hz/50Hz	100-120V/220-240V, 60Hz/50Hz	SE
Power consumption	880VA	850VA	SE
Output frequency	330~460KHz Sinusoid	390~470KHz Sinusoid	SE
Output Mode	**Pure cut:** 350Wmax, Load:500Ω, **Blend 1(macro):** 250Wmax, Load:500Ω, **Blend 2(micro):** 150Wmax, Load:500Ω,	**Low cut:** 300Wmax, Load:300Ω, **Pure cut**:300Wmax, Load:300Ω, **Blend:** 200Wmax, Load:300Ω,	SE
	COAG1(Spray): 120Wmax, Load:500Ω, **COAG2(Forced):** 100Wmax, Load:500Ω, **COAG3(Soft):** 50Wmax, Load:500Ω,	**Low(Desiccate)**:120Wmax, Load:500Ω, Crest factor:5.0 **Med(Fulgurate)**:120Wmax, Load:500Ω, Crest factor:7.0 **High(Spray)**:120Wmax, Load:500Ω, Crest factor:8.0	
	Bipolar1(macro): 100Wmax, Load:100Ω, **Bipolar2(micro):** 100Wmax, Load:100Ω,	**BIPOLAR:** **Low(Precise):**70Wmax, Load:100Ω, **Med(Standard)** : 70Wmax, Load:100Ω, **Macro:**70Wmax, Load:100Ω,	

Items	Proposed device OBS-350A	Predicate device (Force FX)	SE Compare
Open circuit Vp-p(max)	**Monopolar CUT** Pure: 2120V Blend1: 2720V Blend2: 2200V	**Monopolar CUT** Low: 1350V Pure: 2300V Blend: 3300V	SE
	Monopolar COAG COAG1(Spray):4500V COAG2(Forced): 4150V COAG2(soft): 2500V	**Monopolar COAG** Desiccate:3500V Fulgurate: 8500V Spray: 9000V	
	Bipolar: Bipolar1(macro): 500V Bipolar2(micro):350V	**Bipolar:** Precise: 450V Standard: 320V Macro: 750V	
Output waveform	Monopolar and bipolar	Monopolar and bipolar	SE
Safety	ES60601-1:2005/(R)2012 And A1:2012	IEC60601-1:2005	Same
Performance	IEC60601-2-2:2009	IEC60601-2-2:2009	Same
EMC	IEC60601-1-2:2007	IEC60601-1-2:2007	Same

The tissue thermal effects tests by OBS-350A and predicate devices demonstrate the similarity of thermal effects in three tissues, verified substantial equivalence with predicate devices.

8.0 Comparison to Predicate Devices and conclusions

The Electrosurgical Generator model OBS-350A has the same intended use, operating procedures, principles of operation, technology and tissue thermal effects as the predicate devices. The OBS-350A does not raise additional issues of safety or efficacy compared to the predicate devices, and the slight differences have been proved to be substantial equivalence by performance bench test and comparison analyzing. Thus, the subject device and predicate device are substantial equivalence (SE).