DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 2, 2017

ShenZhen Siken 3D Technology Development Co., Ltd.
% Mr. Jet Li
Manager
Guangzhou LETA Testing Technology Co., Ltd
6f, No.1 TianTai Road, Science City, LuoGang District
GuangZhou, CN

Re: K163470
Trade/Device Name: Galvanic Spa, Model: SKB-1405
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: May 9, 2017
Received: May 15, 2017

Dear Mr. Jet 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

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K163470

Device Name
Galvanic Spa, Model: SKB-1405

Indications for Use *(Describe)*
The Galvanic Spa (Model: SKB-1405) is intended for facial stimulation and is indicated for over-the-counter cosmetic use. The anatomical site for application of the Galvanic Spa is the face.

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.

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Chapter 6. 510(k) Summary

Date of the summary prepared: May 1, 2017

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

- Company Name: ShenZhen Siken 3D Technology Development Co.,Ltd.
- Address: Siken Industrial Park, East Avenue No.33 Songgang Street,Baoan District,Shenzhen,Guangdong,China
- Phone: 0755-27697523
- Fax: 0755-27697514
- Contact Person (including title): Kimi xue
- E-mail: sales06@siken3d.com

2. Subject Device Information

- Trade Name: Galvanic Spa, Model: SKB-1405
- Common Name: Galvanic Spa
- Classification name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes
- Review Panel: Neurology, Physical Medicine
- Product Code: NFO
- Regulation Class: 2
- Regulation Number: 882.5890

3. Predicate Device Information

Sponsor	Carol Cole Company
Device Name	NūFACE® Plus
510(k) Number	K103472
Product Code	NFO
Regulation Number	882.5890

Regulation Class	2

4. **Device Description**

Galvanic Spa, Model: SKB-1405 is a non-invasive facial toning device intended for facial stimulation. It produces micro-current discharged through the dual probes that are designed for optimal contact with faces of all shapes and sizes.Micro-current is an aesthetic modality providing electric current in millionths of an ampere and has the ability to increase facial contour and firm the skin and muscles by supplying 0-390 μA.

Galvanic Spa, Model: SKB-1405 is not for use on injured or otherwise impaired skin or muscles, and in any therapy for the treatment, or prevention of any disease. This device is not for use near any devices with Electromagnetic Interference (EMI). This device must only be used for the purpose stated – namely for the stimulation of facial muscles as indicated in the instruction manual for personal beauty purposes. All other uses shall be deemed improper.

5. Intended Use / Indications for Use

The Galvanic Spa (Model: SKB-1405) is intended for facial stimulation and is indicated for over-the-counter cosmetic use. The anatomical site for application of the Galvanic Spa is the face.

6.Design

Galvanic Spa, Model: SKB-1405 is intended for facial stimulation.It has one treatment mode which is micro-current mode.It produces micro-current discharged through the dual probes.The device measures 3.2" L x 6.5" W x 2.2" D. Its two output contacts are made by stainless steel. The device is powered by 3.7V Li-battery,and there are 4 output intensity levels which can be indicated by four LED lamps in the head of device.

7. Materials

There is one kind of patient directly contracting component in the subject device as the following list.

Component of Device Requiring Biocompatibility	**Material of Component**	**Body Contact Category (ISO 10993-1)**	**Contact Duration (ISO 10993-1)**
Electrodes	Stainless steel	Surface-contacting device: skin	Maximum 2 hours (< 24hours)

(Note: The “Massage Head” described in the biocompatibility test reports is mean the electrodes, they are the same part of the device.)

The Nature of body contact is surface, skin contact. And the contact duration is less than 24 hours. According to Table 1 - Initial evaluation tests for consideration in ISO 10993-1, the applicable biological effect is:

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity

1. Cytotoxicity Test

(1) Test Method

MTT Method in ISO 10993-5: Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity, Edition 3.0, 2009;

(2) Passing Criteria

As our subject device is only for limited skin contacting, we set the criteria for NON-TOXIC to be “no more than Grade 2” according to United States Pharmacopoeia.

(3) Test Result

The Cytotoxicity test result showed the device had no toxicity to L929 cell. The test result is passed the criteria.

2. Skin Sensitization Test

(1) Test Method

Guinea Pig Maximization Test in ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization, Edition 3.0, 2010;

(2) Passing Criteria

As our subject device is for limited skin contacting, we set the criteria to be “Grade 0” according to United States Pharmacopoeia.

(3) Test Result

The Skin Sensitization test result for device is Grade 0. The test result is passed the criteria.

3. Skin Irritation Test

(1) Test Method

0.9% Sodium Chlorid Injection and Sesame oil Extract in ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization, Edition 3.0, 2010;

(2) Passing Criteria

As our subject device is for limited skin contacting, we set the criteria to be “0-0.4 for Irritation Index” according to United States Pharmacopoeia.

(3) Test Result

The Skin Irritation test results for Component is 0 for Irritation Index. The test result is passed the criteria.

8.Physical characteristics

Basic Unit Characteristics	
Power Source	3.7V Li-battery
Method of Line Current Isolation	Type BF Applied Part
Patient leakage current	Comply with IEC 60601-1 and IEC 60601-2-10
- Normal Condition	--
- Single Fault Condition	--
Average DC current through electrodes when device is on but no pulses are being applied	0A
Number of channels	1
Number of modes	1
Output Intensity Level	4
Regulated Current or Regulated Voltage?	Current Control
Software/Firmware/Microprocessor Control?	Yes
Automatic Overload Trip?	Yes
Automatic No-Load Trip?	Yes
Automatic Shut Off?	Yes
User Override Control?	Yes
Indicator	Indicates on/off status, low battery, LED of mode information, intensity level information.
Time Range (minutes)	No
Compliance with Voluntary Standards	Yes Comply with IEC 60601-1 and IEC 60601-2-10, IEC 60601-1-2
Compliance* with 21 CFR 898	Yes
Main Unit Weight	248g
Accessories Weight	Charger Adapter: 180g
Main Unit Dimension	3.2" L x 6.5" W x 2.2" D
Charger lead wire length	1.6m
Housing Materials of main unit	Electrodes made from stainless steel.
Accessories Materials	Plastic
Micro-Current Mode Specification	
Waveform and Shape	Pulsed, symmetric biphasic, rectangular
Maximum Output Voltage (+/- 10%)	156mV @ 500Ω 0.78V @ 2kΩ

	2.6V @ 10kΩ
Maximum Output Current (+/- 10%)	0.31mA @ 500Ω 0.39mA @ 2kΩ 0.26mA @ 10kΩ
Net Charge (per pulse)	0 mC @500Ω
Phase Charge	17.1 μC @ 500Ω
Maximum Current Density	0.274mA/cm^2@500Ω (The Electrode Size: 1.13 cm^2)
Maximum Power Density	42.5μW/cm^2@500Ω(The Electrode Size:1.13cm^2)
Pulse Width	55 ms
Pulse Duration	110 ms
Frequency	9.09 Hz±10 %
Contraction and Relaxation Time	Due to different modes. (See below "Program Specification Table")
Additional Features	
Environment for operation	Temperature: 5 ~ 40°C Humidity: ≤ 80% RH
Environment for storage	Temperature: 0 ~ 45°C Humidity: ≤ 93% RH

9. Test Summary

Galvanic Spa, Model: SKB-1405 has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1 and IEC 60601-2-10 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices"
- The waveform test report has also been conducted to verify the output parameters of the device.

10. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of Galvanic Spa, Model: SKB-1405 is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device**	**Remark**
Device Name and Model	Galvanic Spa, Model: SKB-1405	NūFACE® Plus	--
510(k) Number	Applying	K103472	--

Elements of Comparison		**Subject Device**	**Predicate Device**	**Remark**
Manufacturer		ShenZhen Siken 3D Technology Development Co.,Ltd.	Carol Cole Company	--
Intended Use		The Galvanic Spa (Model: SKB-1405) is intended for facial stimulation and is indicated for over-the-counter cosmetic use. The anatomical site for application of the Galvanic Spa is the face.	The NūFACE® Plus Facial Toning Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use. (21 CFR 801 Subpart C). The anatomical site for application of the NOFACE® Plus is the face.	SE
Basic Unit Characteristics				
Power Source(s)		3.7V Li-battery	4 rechargeable AA NiMH batteries	SE Note 1
Method of Line Current Isolation		Type BF Applied Part	Type BF Applied Part	SE
Patient Leakage Current	NC	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	SE
	SFC			
Average DC current through electrodes when device is on but no pulses are being applied		0	0	SE
Number of Output Channels		One channel	One channel	SE
Number of Output Modes		one mode	one mode	SE
Output Intensity Level		4 levels	3 levels	SE Note 3
Synchronous or Alternating?		Alternating	Alternating	SE
Regulated Current or Regulated Voltage?		Both	Both	SE

Elements of Comparison		**Subject Device**	**Predicate Device**	**Remark**
Software/Firmware/Microprocessor Control?		Yes	Yes	SE
Automatic Overload Trip		Yes	Not required due to circuit design	SE Note 1
Automatic No-Load Trip		Yes	Yes	SE
Automatic Shut Off		Yes	Yes	SE
Patient Override Control		Yes	Yes	SE
Indicator Display	On/Off Status	Yes	Yes	SE
	Low Battery	No	Yes	SE Note 1
	Voltage/ Current Level	Yes	Yes	SE
Timer Range		No	Yes(21minutes)	SE Note 3
LCD Display		No	No	SE
Compliance with Voluntary Standards		Yes Comply with IEC 60601-1 and IEC 60601-2-10, IEC 60601-1-2	Yes Comply with IEC 60601-1 and IEC 60601-2-10, IEC 60601-1-2	SE
Compliance* with 21 CFR 898		Yes	Yes	SE
Weight		248g	9 oz without charging base	SE Note 2
Dimensions		3.2" L x 6.5" W x 2.2" D	3" x 5.25" x 1.25"(inch)	SE Note 2
Housing Materials and Construction		Thermo Plastic	Thermo Plastic	SE
Output Specifications				

Elements of Comparison	**Subject Device**	**Predicate Device**	**Remark**
Waveform	Pulsed Biphasic	Pulsed Monophasic	SE Note 3
Shape	Symmetric biphasic, rectangular	Modulated Square	SE Note 3
Maximum Output Voltage (+/- 10%)	156mV @ 500Ω 0.78V @ 2kΩ 2.6V @ 10kΩ	137mV @ 500Ω 769mV @ 2kΩ 3.82V @ 10kΩ	SE Note 3
Maximum Output Current (+/- 10%)	0.31mA @ 500Ω 0.39mA @ 2kΩ 0.26mA @ 10kΩ	274uA @ 500Ω 387uA @ 2kΩ 383uA @ 10kΩ	SE Note 3
Pulse Duration	110ms	119 ms	SE Note 3
Pulse Frequency	9.09 Hz±10 %	8.40 Hz	SE Note 3
Maximum Current Density	0.274mA/cm2@500Ω	0.419mA/cm2@500Ω	SE Note 4
Maximum Power Density	42.5μW/cm2@500Ω	3.22μW/cm2@500Ω	SE Note 4
Contraction and Relaxation Time	Adjustable, due to different levels. (See below “Program Specification Table”)	Adjustable, due to different levels.	SE
Additional Features			
Environment for Operating	Temperature: 5°C~40°C Humidity: ≤80 %	Temperature: 5 ~ 40° C Humidity: 20 ~ 65% RH	SE Note 1
Environment for Storage	Temperature:0~45°C Humidity: ≤ ≤93%	Temperature: 0 ~ 40°C Humidity: 10 ~ 90% RH	SE Note 1
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	SE
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-10,	Comply with IEC 60601-1 and IEC 60601-2-10	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE

Comparison in Detail(s):

Note 1:

"Power Source(s)", "Automatic Overload Trip" , "Operating Environment", "Storage Environment","Housing Materials and Construction" and "Indicator Display of Low Battery and Voltage/ Current Level"are a little different from the predicate devices, it will not affect the main function and the intended use of the device. They all also comply with IEC 60601-1 requirements. So the differences will not raise any safety or effectiveness issue.

Note 2:

Although the "Weight", "Dimensions" of subject device are different from the predicate devices, they are all proved by waveform report and performance report. And they comply with IEC 60601-1 and IEC 60601-2-10 requirements. So the differences of the physics specifications will not raise any safety or effectiveness issue.

Note 3:

Although the "Waveform", "Maximum Output Current", "Maximum Output Voltage","Pulse Duration", "Output Intensity Level","Timer Range" ,"Shape", "Maximum Current Density", "Maximum Power Density"and "Pulse Frequency" of subject device are a little different from the predicate devices, they all comply with IEC 60601-1, IEC 60601-2-10 requirement, So the differences of function specification will not raise any safety or effectiveness issue.

Note 4:

The subject device and the predicate device has the same intended use and the similar technological characteristics of output waveform. And the power density of the subject device and predicate device both conform to FDA Guidance: Maximum Power Density $<$ 0.25 (W/cm^2), and they all comply with IEC60601-1, IEC60601-2-10, so the value of the subject device does not adversely impact safety and effectiveness compared to values of the predicate device.