DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 13, 2017

Zhongshan Bisen Plastic Electronic Products Co., Ltd.
c/o Mr. Ray Wang
Beijing Believe Technology Service Co., Ltd.
5-1206, Build 332, DaFangJu, No. 25 BanBiDian Rd.
LiYuan Town, TongZhou District, Beijing 101121 China

Re: K162489
Trade/Device Name: RED Light Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: December 2, 2016
Received: December 7, 2016

Dear Mr. Wang:

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" (21CFR 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)*

K162489

Device Name
RED Light Device

Indications for Use *(Describe)*
The RED Light Device is an OTC device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

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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"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."

Tab #7 510(k) Summary

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

The assigned 510(k) Number: K162489

1. Date of Preparation

   08/23/2016

2. Sponsor

Zhongshan Bisen Plastic Electronic Products Co.,Ltd.

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3. Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: RED Light Device
Common Name: Light Emitting Diode (LED) Device
Model(s): BZ-0606

Regulatory Information:
Classification Name: Light Based Over The Counter Wrinkle Reduction
Classification: II;
Product Code: OHS;
Regulation Number: 21 CFR 878.4810；
Review Panel: General & Plastic Surgery;

Indication for Use Statement:
The RED Light Device is an OTC device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

5. Device Description

The proposed device, RED Light Device is a battery operated device that uses low power light spectrum at red and infrared LED, at wavelength of 633 ±5nm, 830 ±5nm emitting optical power in a uniform distribution with no hot spots.
The device is composed of a handpiece for delivery of light energy, base unit for charging and storage when not in use, and A.C. charging adapter.
It is a hand held light emitting diode (LED) device for the treatment of periorbital wrinkles designed for home-use.

The proposed device is NOT for life-supporting or life-sustaining, not for implant.
The proposed device is NOT provided sterile and is NOT a reprocessed single-use device.

6. Identification of Predicate Device

Predicate
510(k) Number: K152332
Product Name: Perfectio LED Infrared Device
Manufacturer: OMM IMPORTS INC DBA ZERO GRAVITY

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:2012, Medical electrical equipment– Part 1: General requirements for basic safety, and essential performance.
IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
IEC 60601-2-57:2011, Medical electrical equipment - Part 2-57: Particular requirements for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.
IEC 60601-1-11:2010, Medical electrical equipment - Part 1-11: General requirements for medical device equipment and medical electrical systems used in the home healthcare environment.
IEC 62471:2006 , Photobiological Safety of lamps and lamp systems.
ISO 10993-5: 2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
Performance Test: Temperature Test

A Usability/Label Comprehension Study was conducted with 35 participants.
The results of the study showed that (100%) were able to:
-Correctly self-select as being an appropriate user of the device.
-Correctly demonstrate how to set up the device, perform the Light Sensitivity Test, operate the device (apply Tx), and clean the device.
And that (95%) of participants were able to correctly answer each question for the Questionnaire portion of the Study.

8. Clinical Test Conclusion

Clinical data was not included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device	Remark
Product Code	OHS	OHS	SE
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SE
Class	2	2	SE
OTC use	Yes	Yes	
Indication for Use	The RED Light Device is an OTC device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.	Perfectio LED infrared device is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.	SE

Table 2 Performance Comparison

ITEM	Proposed Device	Predicate Device	Remark
Handheld	Yes	Yes	SE
Contacting Materials	ABS & Stainless Steel	ABS & Stainless Steel	SE
Measurement wavelength	Red: 633 ±5nm Infrared: 830 ±5nm	Red: 633 ±5nm Infrared: 830 ±5nm	SE
Light Source	Light Emitting Diode (LED)	Light Emitting Diode (LED)	SE
Waveform	Constant	Constant	SE
Energy Source	25 LEDs over 17 cm^2	25 LEDs over 17 cm^2	SE
Power Density	125 mW/cm2 70 mW/cm2 (633 nm); 55 mW/cm2 (830 nm)	125 mW/cm2 70 mW/cm2 (633 nm); 55 mW/cm2 (830 nm)	SE
Power Supply	Adaptor:100~240V AC 50/60Hz Lithium battery: 2x3.7V	Adaptor:100~240V AC 50/60Hz Lithium battery: 2x3.7V	SE
Initial Treatment Course	For the first month (4 weeks), treatment should be performed 3 times a week for 15-20 minutes each time.(5-7 minutes on each treatment zone).	For the first month (4 weeks), treatment should be performed 3 times a week for 15-20 minutes each time.(5-7 minutes on each treatment zone).	SE
Maintenance Regime	Individuals with periorbital lines and wrinkles	Individuals with periorbital lines and wrinkles	SE

Table 3 Safety Comparison

ITEM	Proposed Device	Predicate Device	Remark
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	SE
	Comply with IEC 60601-1-11	Comply with IEC 60601-1-11	
	Comply with IEC 62471	Comply with IEC 62471	
	Comply with IEC 60601-2-57	/	
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	SE
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SE
Level of Concern of the Software	Moderate	Moderate	SE

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.