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

April 25, 2017

Oriental Inspiration Limited
Andy Wu
Director
Unit 607, The Lakeside 2, West Wing, No. 10
Science Park West Avenue
Hong Kong, CN

Re: K170260
Trade/Device Name: BC-001+ Acne Purifier
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: OLP
Dated: November 10, 2016
Received: January 27, 2017

Dear Andy Wu:

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,

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)*
K170260

Device Name
BC-001+ Acne Purifier

Indications for Use *(Describe)*
BC-001+ Acne Purifier is intended/indicated for over-the-counter use in the treatment of mild to moderate acne.

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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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 21 CFR 807.92

1. Submitter of 510(K):

Company Name	:	Oriental Inspiration Limited
Address	:	Unit 607, The Lakeside 2, West Wing, No. 10 Science Park West Avenue, Hong Kong Science Park, Shatin, N.T. Hong Kong.
Contact person	:	Mr. Andy Wu
TEL	:	+(852) 2654 0872
FAX	:	+(852) 2687 4148
E-mail	:	andy_wu@netop.com.hk
Date Prepared	:	25th April, 2017

2. Proposed Device and code:

Device Trade Name	:	BC-001+ Acne Purifier
Regulation Medical Specialty	:	General & Plastic Surgery
Product Code	:	OLP
Regulation number	:	878.4810
Device Class	:	2

3. Predicate Device:

510(K)	Trade or Proprietary or Model Name	Manufacturer
K142246	LightStim for Acne/ LightStim for Acne Mini	LED Intellectual Properties, LLC
K153081	Clear Bi-Light	Michael Todd, LP
K152889	Sonilase Blue-UV Clean Plus Model-SL113BUV+	Biorenew Labs, LLC

4. Description of Proposed Device:

This devices adopts narrow band of low level Red 660nm and Blue light (415nm), the selected light

can get about 3~5mm depth into skin. The BC-001+ Acne Purifier is a hand-held device consisting of a low intensity light emitting diode (LED) lamp that is intended/indicated for over-the-counter use in the treatment of mild to moderate acne. Finally, this product belongs to the low level light therapy, it is safe to use on acne treatment. The device has a power on/off switch, treatment button, battery status indicator, Micro- USB socket for battery charging.

5. Intended Use

BC-001+ Acne Purifier is intended for over-the-counter use in the treatment of mild to moderate acne.

6. Technical and Performance

The following table compares the device to the predicate devices with basic technological characteristics.

Parameter	New Device	Predicate Device	Predicate Device	Predicate Device	Remark
510(k) Number	(to be assigned)	K142246	K153081	K152889	--
Device Name and Model	BC-001+ Acne Purifier	LightStim for Acne/ LightStim for Acne Mini	Clear Bi-Light	Sonilase Blue-UV Clean Plus Model-SL113BUV+	--
Manufacturer	Oriental Inspiration Limited	LED Intellectual Properties, LLC	Michael Todd, LP	Biorenew Labs, LLC	--
Regulation Number	878.4810	878.4810	878.4810	878.4810	--
Classification	2	2	2	2	--
Intend of use	BC-001+ Acne Purifier is intended/indicated for over-the-counter use in the treatment of mild to moderate acne.	LightStim for Acne/ LightStim for Acne Mini is an over-the-counter hand-held device intended for the use in the treatment of mild to moderate acne.	The Clear Bi-Light is indicated for the treatment of mild to moderate inflammatory acne.	The Sonilase Blue-UV Clean Plus is a handheld OTC device intended to emit energy in the blue region of the light spectrum for use in the treatment of mild to moderate acne vulgaris	SE
Over-the-counter use?	Yes	Yes	Yes	Yes	SE
Overall design	Lithium-ion rechargeable battery AC charger: 100-240V at 50-60Hz, 500	Mains powered handheld device applied to the face providing LED light	Lithium-ion rechargeable battery AC charger: 100-240V at 50-60Hz, 500	One 7.4V rechargeable Lithium-ion battery	Same as K153081 and K152889,but different with

	mA	output.	mA		K142246, Note 1
IEC 60601 Compliant	Yes	Yes	Yes	Yes	SE
Handheld	Yes	Yes	Yes	Yes	SE
Dimensions	70mm*70mm*23mm	unknown	64 mm *35 mm *14.6 mm	Not stated	Different, Note 1
Performance Data	Complies with applicable performance specifications and usability requirements				SE
Performance Features					
Treatment Area (cm^2)	9.1 [cm^2]	16.6 [cm^2]	20 [cm^2]	Over 9.6cm^2	Different with K153081, K152889 and K142246, but within the scope of treatment area of predicate device. Note 1
Wavelength(s) (nm) Blue Red	 415 ± 5 660 ± 5	 411 ± 4 640 ± 4	 405-420 630-660	 415 ± 5	Blue light is same as the K153081, K152889 and K142246, And red light is same as the k153081
Treatment Timer	Up to 1.5 minutes per area	Up to 3 minutes per area	Up to 3 minutes per area	4 minutes per area, daily	Different with K141242, and K140381, Note 1,
Dose rate (mW/cm^2) Blue Red	 50 (blue) 23 (red)	 12.4 (blue) 6.3 (red)	 31.1 (blue) 54.6 (red)	 50 (blue)	Blue dose rate is same as K152889. Red dose rate is within the scope of K153081, Note 1

Note 1

Although it is a little bit different from the predicate devices, it will not affect the main function and the intended use of the device. They all also comply with safety and performance requirements. So the differences will not raise any

safety or effectiveness issues.

7. PERFORMANCE DATA

The testing for BC-001+ Acne Purifier included performance, software, electrical safety, EMC, biocompatibility and bench. BC-001+ Acne Purifier passed all testing in support of the substantial equivalence determination:

7.1. Biocompatibility testing

The biocompatibility evaluation for the BC-001+ Acne Purifier was conducted in accordance with International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process." As dictated by the application and duration of contact with the intact skin, the enclosure of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

7.2. Electrical safety and electromagnetic compatibility

Electrical safety, performance and EMC testing were conducted on the BC-001+ Acne Purifier. The device with compliance with the IEC 60601-1, IEC 60601-1-11, IEC 60601-2-57, and IEC 62471 standards for safety and the EN 60601-1-2 standard for EMC and the IEC 62133 standard for battery safety.

7.3. Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern.

7.4. Usability Testing

Usability testing according to following FDA Guidance 1757, Applying Human Factors and Usability Engineering to Optimize Medical Device Design, was conducted.

8. Conclusions

The proposed device has the same intended use and similar characteristics as the predicate devices, the LightStim for Acne/ LightStim for Acne Mini device (K142246), Clear Bi-Light device (K153081) and Sonilase Blue-UV Clean Plus (K152889). Meanwhile, performance testing, bench testing, and safety report documentation supplied in this submission demonstrates that any differences in their

technological characteristics do not raise any new questions of safety or effectiveness. Based on performance testing, the proposed device is Substantially Equivalent (SE) to the predicate devices.