DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 21, 2016

Zuko, Inc.
% Ms. M. Joyce Heinrich
President
Texas Applied Biomedical Services (T.A.B.S.)
12101 Cullen Blvd, Suite A
Houston, Texas 77047

Re: K160691
Trade/Device Name: Acne Light Therapy Wand
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: May 16, 2016
Received: May 19, 2016

Dear Ms. Heinrich:

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 -A

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)*
K160691

Device Name
Acne Light Therapy Wand

Indications for Use *(Describe)*
The Acne Light Therapy Wand is indicated to treat mild to moderate inflammatory 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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510(k) Summary for Acne Light Therapy Wand

1. Submission Sponsor

Zuko, Inc.

2. Submission Correspondent

Texas Applied Biomedical Services (T.A.B.S.)
12101 Cullen Blvd, Suite A
Houston, Texas 77047
Phone: (713) 734-4433
Fax: 1-866-362-3968
Contact: M. Joyce Heinrich, President
Email: Tabsii2@comcast.net

3. Date Prepared

17 June 2016

4. Device Name

Trade/Proprietary Name: Acne Light Therapy Wand
Common/Usual Name: Acne Light Therapy System
Classification Name: Over-the-counter powered light based laser for acne[1]
Classification Regulation: 21CFR 878.4810
Classification Panel: General and Plastic Surgery
Product Code: OLP
Device Class: II
FDA Establishment Registration #: To be obtained after clearance

5. Predicate Devices

- Tanda Zap Mini Skincare System 510(k) number K124042, cleared on April 02, 2013, manufactured by Syneron Beauty Inc.
- LightStim for Acne 510(k) number K142246, cleared on January 29, 2015, manufactured by LED Intellectual Properties, LLC

6. Device Description

[1] NOTE: OLP is the best description and closest match to this device. However the device uses LED light sources; there is no coherent (laser) light involved.

The Acne Light Therapy Wand uses known LED light therapy technology for the treatment of acne. A combination of blue light and red light is emitted. The Acne Light Therapy Wand device does not emit any ultraviolet (UV) light. UV light is defined as light with the range of 100-400nm. To use the Acne Light Therapy Wand device, users place the device over the treatment area and press the "On" button on the device to start treatment. The device will automatically turn off after each treatment cycle.

7. Intended Use

The Acne Light Therapy Wand is indicated to treat mild to moderate inflammatory acne.

8. Technological Characteristics and Substantial Equivalence

This document uses the term "substantial equivalence" as defined in 21 CFR 807.87 and not as defined in Title 35 of the U.S. Code.

The Acne Light Therapy Wand device is substantially equivalent to the Tanda Mini Skincare System and the LightStim for Acne devices in safety and efficacy. All are hand-held, LED light therapy wand devices indicated for the treatment of mild to moderate inflammatory acne.

The properties and characteristics of the subject and predicate devices are compared in the table below.

Table 1. Acne Light Therapy Wand vs. Tanda Mini Skincare and LightStim for Acne Systems

Trade Name	Acne Light Therapy Wand	Tanda Mini Skincare System	LightStim for Acne
510(k) Number	K160691	K124042	K142246
Regulation Number	21CFR 878.4810	21CFR 878.4810	21CFR 878.4810
Over-the-counter use?	Yes	Yes	Yes

Overall design	Portable battery powered device applied to the face providing LED light output.	Portable battery powered device applied to the face providing LED light output.	Mains powered hand-held device applied to the face providing LED light output.
Materials	Polypropylene, Polycarbonate, Aluminum	Polypropylene, Polycarbonate	Polypropylene, Polycarbonate,
Wavelength	442 ± 4nm 633 ± 4nm	415 ± 4nm	411 ± 4 nm 640 ± 4 nm
Treatment Area (cm^2)	1.594	4.155	16.6
Dose Rate (mW/cm^2)			
Blue	26.5	36.2	12.4
Red	7.5	n/a	6.3
Total	34.0	36.2	18.7
Dose (J/cm^2)			
Blue	9.6	13.0	8.9
Red	2.6	n/a	4.5
Total	12.2	13.0	13.4
Performance Data	Complies with applicable performance specifications and usability requirements.	Complies with applicable performance specifications and usability requirements.	Complies with applicable performance specifications and usability requirements.
IEC 60601 Compliant	Yes	Yes	Yes
Electrical Power	1 AAA alkaline batteries	3 AAA alkaline batteries	AC/DC adapter

User Interface	On/off button, located on the device. Device turns on with a push of the button and turns off automatically. There are no other user selectable parameters.	On/off button, located on the device. Device turns on with a push of the button and turns off automatically. There are no other user selectable parameters.	On/off button, located on the device. Device turns on/off with a push of the button. There are no other user selectable parameters.

9. Non-Clinical Testing

The Acne Light Therapy Wand device conforms to the requirements of IEC 60601-1 3rd edition, IEC 60601-1-2, and IEC 62471.

Additionally, a Self Selection and Usability Study was conducted with laypersons and demonstrated that the Acne Light Therapy Wand is an easy to use device and the packaging and labeling are appropriate for and easily understood by the layperson.

10. Clinical Testing

The Acne Light Therapy Wand is substantially equivalent to predicate devices currently in commercial distribution in the USA. Therefore, clinical testing of the device was not conducted.

11. Conclusion

By definition, a device is substantially equivalent to a predicate devices when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device may have the same intended use and different technological characteristics if they can be demonstrated that the device is substantially equivalent to the predicate device(s), and that the new device does not raise different questions regards its safety and effectiveness as compared to the predicate device.

We have shown in this 510(k) submission that the Acne Light Therapy Wand has the same intended use and technological characteristics as the predicate devices and does not raise any questions regarding its safety and effectiveness. The Acne Light Therapy Wand device, as designed and manufactured, has been found to be substantially equivalent to the predicate devices.