August 30, 2018

Uplevity, Inc.
% Marc Sanchez
Regulatory Counsel
Contract In-House Counsel and Consultants, LLC
(d/b/a FDA Atty)
1717 Pennsylvania Ave., Ste. 1025
Washington, District of Columbia 27517

Re: K180888
Trade/Device Name: LYFT
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: August 1, 2018
Received: August 1, 2018

Dear Marc Sanchez:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180888

Device Name
LYFT

Indications for Use *(Describe)*
The LYFT device is intended to be used:

LED functional mode
To emit energy in the red and blue region of the spectrum, specifically to treat mild to moderate acne on the face.
To emit energy in the red region of the spectrum for the treatment of periorbital wrinkles.

Micro Vibration functional mode
As an electrically powered device intended for medical purposes to relieve minor aches and pains.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

UPLEVITY, Inc.

5. 510(K) Summary

The following information is provided as required by 21 CFR 807.92 for the **LYFT 510(k)** premarket notification.

Applicant: UPLEVITY, Inc.
40 Marshfield Rd
Niantic, CT 06357
Establishment Registration: 3013515062

Manufacturer: Shenzhen Perfect Idea Technology Co., Ltd.
4f, Building 1, Fuhua Industrial Park, Tangwei, Fuyong, Bao'an
Shenzhen Guangdong, 518103 CHINA
Establishment Registration: Awaiting Assignment of Registration Number

Contact: Marc C. Sanchez, Esq.
Contract In-House Counsel and Consultants, LLC
53516 Bickett Chapel Hill NC 27517
Ph: 202.765.4491
E-mail: msanchez@fdaatty.com

Date of Submission: August 29, 2018

Proprietary Name: LYFT

Common Name: Over-The-Counter Powered Light Based Laser For Acne

Regulation Number: 21 CFR 878.4810

Regulatory Class: Class II

Product Code: OLP

Predicate Device(s): Ultra Renew Plus (K132833)

Device Description:

The LYFT is a hand-held, rechargeable Li-Polymer battery powered device used for the treatment of mild to moderate acne, preorbital wrinkles, and the relief of minor aches and pains. The LYFT devices combines two (2) functional modes of operation, LED and micro vibration. The LED functional mode provides narrow bandwidth spectral output in the blue (430 ± 5 nm) and red (625 ± 5 nm) ranges. The micro vibration functional mode operates at a fixed frequency of 3 MHz ± 5%. The LYFT device uses a supplied power adaptor and is rechargeable.

Intended Use: The LYFT device is intended to be used:

- LED functional mode
  - To emit energy in the red and blue region of the spectrum, specifically to treat mild to moderate acne on the face.
  - To emit energy in the red region of the spectrum for the treatment of periorbital wrinkles.
- Micro Vibration functional mode
  - As an electrically powered device intended for medical purposes to relieve minor aches and pains.

Summary of Non-Clinical Test Reports

The following tests were performed on the LYFT device and the test results show that the subject device is substantially equivalent to the predicate devices in the market.

In Vitro Cytotoxicity	ISO 10993-5 for In Vitro Cytotoxicity standards
Skin Sensitization Test and Skin Irritation Tests	ISO 10993-10 Tests for Irritation and Skin sensitization
Electromagnetic Compatibility Test	IEC 60601-1-2 standards
Electrical Safety and Essential Performance Test	IEC 60601-1; IEC 60601-2-57; IEC 60601-1-11 standards
Usability	IEC 62366-1
Software Verification and Validation Test	FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Device"

Summary of Technological Similarities/Differences

The LYFT emits visible and/or infrared energy and micro vibration functional mode operates at a fixed frequency the same the Ultra Renew Plus. Both devices use similar outputs and have similar technical characteristics. The intended use is the same on both devices. There may be minor differences in labeling but this does not raise any new questions of safety or effectiveness.

Table 1
Technological Characteristics

Device Name/Model	LYFT	Ultra Renew Plus
510(k) Number	t/b/d	K132833

Indication for Use	Full face wrinkles and moderate to mild acne. Relieve minor aches and pains.	Full face wrinkles and moderate to mild acne. Relieve minor aches and pains.
Power Source	AC to DC and Rechargeable battery	AC to DC
Wavelengths	430 and 625nm	450 and 650nm
Effective power for blue and red LEd light	0.9W and 0.8W	
Micro Vibration Function Mode	3 MHz ± 5%	3 MHz ± 5%
Lightsource	LED/infrared bulbs	LED/infrared bulbs
Handheld	YES	YES

Conclusion

Therefore, taking into consideration Table 1 for Substantial Equivalence, an analysis of safety, indications, intended uses, performance, and technological properties, the LYFT raises no different questions of safety or effectiveness and has been found to be substantially equivalent to the predicate devices.