June 29, 2021

YRS Group Inc.
% Doris Dong
Senior Regulatory Affairs Project Manager
Shanghai CV Technology Co., Ltd.
Room 903, No. 19 Dongbao Road, Songjiang Area
Shanghai, Shanghai 201613
China

Re: K210954
Trade/Device Name: Synergy
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: March 3, 2021
Received: March 30, 2021

Dear Doris Dong:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210954

Device Name
SYNERGY

Indications for Use *(Describe)*
The SYNERGY is an Over-the-Counter (OTC) device intended for the use in treating wrinkles on 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K210954
Date:	June 15th, 2021
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Owner:	YRS Group Inc 4480 Delancey Dr Ste 14, Las Vegas, NV, 89103-3753, US Tel: (702) 4268921 Email: usa@opatra.com
Contact:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add: Room 903, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description

Proprietary Name:	SYNERGY
Model:	BP-1818R1
Common Name:	Red/IR Light Therapy Device
Classification Name:	Light Based Over The Counter Wrinkle Reduction
Regulation Number:	21 CFR 878.4810
Product Code:	OHS
Device Class:	II
Review Panel:	General & Plastic Surgery
Device Description:	The SYNERGY is an over-the-counter, battery powered, hand-held light emitting diode (LED) device that emits light energy in the red and infrared spectrum for the treatment of wrinkles on the face. The SYNERGY components include an applicator, a charging station and an adaptor. The treatment surface is applied directly to the skin to ensure consistent administration of light during each treatment. The device does not contain any user repairable components. The device is sold for Over the Counter (OTC) use.
Indications for use:	The SYNERGY is an Over-the-Counter (OTC) device intended for the use in treating wrinkles on the face.

3. Substantial Equivalence to Predicate device

Detailed comparison data is included in “Section 10 - Substantial Equivalence Discussion” of this 510(k) submission.

Table 1-

Parameters	New Device	Predicate Device	Remark
510(k) number	K210954	K172909	--
Device name	SYNERGY	Elevare Plus	--
Product code	OHS	OHS	Same

Class	II	II	Same
Indication for use	The SYNERGY is an Over-the-Counter (OTC) device intended for the use in treating wrinkles on the face.	The Elevare Plus is an Over-the-Counter (OTC) device intended for the use in treating wrinkles on the face.	Same
Anatomical site	Entire Face	Entire Face	Same
Handheld	Yes	Yes	Same
wavelengths	610, 630, 660, 850nm ±5nm	610, 630, 660, 850nm ±5nm	Same
Irradiance source	LED	LED	Same
Visible light LEDs	Yes	Yes	Same
LED Array	16 LEDs, Over 17cm^2	25 LEDs, Over 17cm^2	Similar Note 1
Energy Level (mW/cm^2)	65 mW/cm^2 (± 5 mW/cm^2)	65 mW/cm^2 (± 5 mW/cm^2)	Same
Power Supply	Li-Ion rechargeable batteries	Li-Ion rechargeable batteries	Same
Treatment Time	3 minutes each area each mode, 5 days per week for 8 weeks	3 minutes daily, 5 days per week for 8 weeks	Similar Note 2
Target population	Individuals with wrinkles on the face	Individuals with wrinkles on the face	Same
Location for use	OTC	OTC	Same
Main material	ABS and stainless steel	ABS and stainless steel	Same

Summary of the technological characteristics of the device compared:

Note 1:

The subject device is slightly different from the predicate device in terms of number of LEDs and appearance. The subject device has 16 LEDs while the predicate device has 25 LEDs,but they have the same energy density, and both of them have passed the tests of IEC 60601-1 and IEC 62471, these differences will not raise any new issues of safety or effectiveness.

Note 2:

The treatment time of the proposed device is slightly different from the predicate device. The predicate device uses 4 wavelengths of LEDs to work simultaneously for 3 minutes, while the proposed device sets 4 wavelengths in two modes (Mode 1: 610nm & 630nm, Mode 2: 660nm & 850nm), each mode is treated for 3 minutes. Considering both of them have the same treatment time of each wavelength, the energy produced by these wavelengths, power density and maintenance time are also the same, it can be concluded that the same treatment effect as the predicate device can be achieved. In addition, the proposed device has passed the tests of IEC 60601-1 and IEC 62471. Based on above analysis, these differences will not cause any safety and effectiveness issues.

4. Non-clinical Testing

The conclusions drawn from the non-clinical testing below demonstrate that the SYNERGY is substantially equivalent to the predicate devices K172909. The SYNERGY has been tested and conforms to international consensus standards:

Electrical safety:

- ANSI AAMI ES60601-1: 2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD);

EMC:

- ANSI AAMI IEC 60601-1-2:2014, Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests;

Additional safety testing:

- ANSI AAMI IEC60601-1-11 2015 Medical Electrical Equipment -- Part 1-11: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment;
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems;
- IEC 62133-2, Edition1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems;

Biocompatibility testing:

- ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization. (Biocompatibility)

The SYNERGY has been tested to ensure the device meets specifications:

Performance testing

- Software Validation Testing

The SYNERGY's software was tested and validated in accordance with FDA's "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices."

- Skin Temperature Testing

Temperatures of treatment surface were recorded every 1 minute, up to 15 minutes, using a calibrated digital temperature sensor. The test results concluded that the SYNERGY was within specification of 41± 2℃ and did not elevate skin temperature above 43℃.

5. Conclusions

Based upon comparison to the predicate devices, the SYNERGY has the same intended uses, with similar technological characteristics as predicate devices. The subject device SYNERGY is substantially equivalent to the predicate device K172909.