July 22, 2022

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

Re: K220064
Trade/Device Name: Synergy Marble (Model: Opasm)
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, OLP
Dated: June 27, 2022
Received: July 5, 2022

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,

Jianting Wang
Acting 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)*
K220064

Device Name
SYNERGY MARBLE

Indications for Use *(Describe)*
SYNERGY MARBLE is a hand-held device for over-the counter aesthetic purposes. The device red light and amber light are intended for the use in treating wrinkles on the face, and the blue light is intended for the treatment of the 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

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K220064
Date:	July 21, 2022
Type of 510(k) Submission:	Traditional 510(k)
Basis for 510(k) Submission:	New device
Owner:	YRS Group Inc. 5151 S Procyon St, Suite 105, Las Vegas, NV 89118, US Tel: 1-702 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 MARBLE
Model:	OPASM
Classification Name:	Light Based Over The Counter Wrinkle Reduction (OHS) Over-The-Counter Powered Light Based Laser For Acne (OLP)
Regulation Number:	21 CFR 878.4810
Product Code:	OHS, OLP
Device Class:	II
Review Panel:	General & Plastic Surgery
Device Description:	The SYNERGY MARBLE is an over-the-counter, battery powered, hand-held light emitting diode (LED) device that emits light energy in the red, blue and amber spectrum for the treatment of wrinkles or mild to moderate inflammatory acne on the face. The SYNERGY MARBLE 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 as Over the Counter (OTC).
Indications for use:	SYNERGY MARBLE is a hand-held device for over-the counter aesthetic purposes. The device red light and amber light are intended for the use in treating wrinkles on the face, and the blue light is intended for the treatment of the mild to moderate inflammatory acne.

3. Substantial Equivalence Devices Identification

Predicate Device:	K202055- Looper (Model: ZX-579S)- Heat In A Click LLC
Reference Device:	K190443- MMSphere™ - Galactic Beauty, LLC

4. Substantial Equivalence to Predicate device

Parameters	New Device	Predicate Device	Reference Device	Remark
510(k) number	K220064	K202055	K190443	--
Device name	SYNERGY MARBLE	Looper	MMSphere™	--
Model	OPASM	ZX-579S	/	--
Owner	YRS GROUP INC	Heat In A Click LLC	Galactic Beauty, LLC	--
Product code	OHS, OLP	OHS, OLP	OHS, OLP	Same
Class	II	II	II	Same
Indication for use	SYNERGY MARBLE is a hand-held device for over-the counter aesthetic purposes. The device red light and amber light are intended for the use in treating wrinkles on the face, and the blue light is intended for the treatment of the mild to moderate inflammatory acne.	Looper (Model: ZX-579S) is a hand-held device for over-the counter aesthetic purposes. The Photon mode red light is intended for the use in treating wrinkles on the face, and the blue light is intended for the treatment of the mild to moderate inflammatory acne.	MMSphere™ Light Therapy Device emits energy in the red, blue and amber regions of the spectrum, specifically indicated to treat wrinkles and/or mild to moderate acne. The MMSphere™ is designed to be used for 20 minute treatments three to seven times per week.	Similar
Use	Over the Counter	Over the Counter	Over the Counter	Same
Anatomical site	Entire Face	Entire Face	Entire Face	Same
Type	Hand-held	Hand-held	Handheld and stationary	Same
Target Population	Individuals with wrinkles and/or mild to moderate acne on the face	Individuals with wrinkles and/or mild to moderate acne on the face	Individuals with wrinkles and/or mild to moderate acne on the face	Same
Irradiance source	LED	LED	LED	Same
Visible light LEDs	Yes	Yes	Yes	Same
LED Array	8 LEDs, Over 17cm^2	22 LEDs over 12±10%cm^2	Not publicly available	Similar
Working Modes and Wavelengths	Mode 1: Red (625nm±3nm) Mode 2: Blue (465nm±3nm) Mode 3: Amber (605nm±3nm)	SONIC Mode: 5 intensity levels PHOTON Mode (two modes): Red: 630nm±10nm Blue: 415±10nm	Red: 625nm Blue: 465nm Amber: 605nm	Similar
Energy density	Red: 55.3mW/cm^2±10%	Red: 55mW/cm^2±10%	Red: 2.45mW/cm^2	Similar

	Blue: 48.2mW/cm^2±10% Amber:38.3mW/cm^2±10%	Blue: 48mW/cm^2±10%	Blue: 1.33mW/cm^2 Amber:Not publicly available	
Treatment Time	3 minutes per target area; 2 treatments per week for 6 weeks	3 minutes per target area; 2 treatments per week for 6 weeks	20 minutes/day, 120days	Same
Power Supply	Lithium battery	Lithium battery	Lithium battery	Same
Main material	ABS	ABS Plastic & Stainless Steel	Not publicly available	Similar

5. Non-clinical Testing

The SYNERGY MARBLE has been evaluated the safety and performance by lab bench testing and conforms to the following 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:

- IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests;

Additional safety testing:

- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability;
- IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for 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.
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

6. Conclusions

The conclusion drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K202055 and reference device K190443.