March 3, 2022

Y & J Bio Co., Ltd.
℅ Paweena U-Thainual
CEO
MDR Solutions Co., Ltd.
1435 Kanchanapisek Rd., Bang Khae Nuea
Bang Khae, Bangkok 10160
Thailand

Re: K213285
Trade/Device Name: easy Claire
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: February 14, 2022
Received: February 16, 2022

Dear Paweena U-Thainual:

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)*

K213285

Device Name
easy Claire

Indications for Use *(Describe)*
The easy Claire is an over-the-counter medical device intended for the use in the treatment of full face wrinkles.

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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"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."

5. 510(k) Summary

1. General Information

Applicant/Submitter:	Y&J BIO Co., Ltd.
Address:	B-916 ,947, Hanam-daero, Hanam-si, Gyeonggi-do, Republic of Korea Tel) +82-31-5180-3490
Contact Person: Address:	Paweena U-Thainual, PhD MDR Solutions Co., Ltd. 1435 Kanjanapisek Rd., Bang Khae Nuea Bang Khae, Bangkok, 10160 THAILAND Tel: +662-804-2101 Email: paweena@mdrsolutions.co.th
Preparation Date:	February 11, 2022

2. Device Name and Code

Device Trade Name:	easy Claire
Common Name:	Light-based mask
Classification Name:	Light Based Over The Counter Wrinkle Reduction
Product Code:	OHS
Regulation Number:	878.4810
Classification:	Class II
Review Panel:	General & Plastic Surgery

3. Predicate Devices

easy Claire is substantially equivalent to the following device:

Table 5.1 Predicate devices

Applicant	Device Name	510(k) Number
Trophy Skin, Inc.	Rejuvalite MD	K133896

Table 5.2 Reference device

Applicant	Device Name	510(k) Number
Pulsaderm LLC	Pulsaderm Wrinkle Mask 28 and Wrinkle Mask 72	K163329

4. Device Description

The easy Claire is a device that allows the emission of 630nm LED light and 850nm IRED light on the face, which induces photobiological effects for the treatment of facial wrinkles. The easy Claire is an over-the-counter device and consists of a collection of 99 LEDs (630nm) and 99 IREDs (850nm) for the treatment of facial wrinkles.

Users place the lightweight mask over the face and use the touch switch button to operate the easy Claire. The device will automatically turn off after treatment. To prevent irradiation of LED lights to the eye during the treatment, easy Claire has a protective eye-shield that blocks light from LEDs.

The device is powered by the internal rechargeable lithium-ion battery which is recharged by the specified external adapter with Input AC 100-240V, 50/60Hz, and Output DC 5V, 2A.

5. Indications / Intended Use

The easy Claire is an over-the-counter medical device intended for the use in the treatment of full-face wrinkles.

6. Technical Characteristics in Comparison to the Predicate and Reference Devices

The easy Claire is substantially equivalent to the following legally marketed predicate devices.

Table 5.3. Side-by-side comparison with the predicate and reference device

	Proposed Device K213285	Predicate Device K133896	Reference Device K163329
Company	Y&J BIO Co., Ltd.	Trophy Skin, Inc.	Pulsaderm LLC
Product name	easy Claire	Rejuvalite MD	Pulsaderm Wrinkle Mask 28 and Wrinkle Mask 72
Product code	OHS	OHS	OHS
Regulation number	878.4810	878.4810	878.4810
Classification	Class II	Class II	Class II
Intended Use	The easy Claire is an over-the-counter medical device intended for the use in the treatment of full face wrinkles	The Rejuvalite MD is an Over-the-Counter device that is intended for the use in the treatment of full face wrinkles.	The Pulsaderm Wrinkle Masks 28 and 72 are intend for the use in the treatment of facial wrinkles and for people with Fitzpatrick Skin Types I, II and III
Type of use	OTC	OTC	OTC
Technological characteristics			
Wavelength	RED(630nm)	RED(600, 622, 660 nm)	RED(620-630 nm)

	IR(850nm)	IR(820nm)	IR(850nm)
LED power	20±20% mW/cm^2 total	62mW/cm^2 total	21.18-25.32mW/cm^2 total
Treatment time	9 minutes every day for 8 weeks	3 minutes daily 5 days per week for 8 weeks	15 minutes every day
Standard dose in Joules	10.8±20% J/cm^2	11.2J/cm^2	19J-22.82J/cm^2
Face mask	Yes	No	Yes

7. Performance Data

Non-clinical tests: In order to demonstrate the safety and effectiveness of easy Claire, various test has been conducted using following consensus standards"

- IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.
- IEC 60601-1-2: 2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances.
- IEC 60601-1-6:2010, AMD1:2013, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- IEC 60601-1-11:2015, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601- 2-57:2011, Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.
- IEC 62471:2006, Photobiological safety of lamps and lamp systems is evaluated according to FDA-recognized consensus standard.
- ISO 10993-5: 2009, Tests for in vitro cytotoxicity
- ISO 10993-10: 2010, Tests for irritation and skin sensitization
- Risk management was recorded by referring to ISO 14971:2007.

8. Substantial Equivalence

The intended use of the easy Claire is within the scope of the predicate devices. easy Claire, from both a design and clinical perspective, uses similar technology as the cited predicate devices. Based upon the predicted overall performance characteristics for the easy Claire, Y&J BIO Co., Ltd. believes that no significant differences exist in the usage of its underlying technological principles between easy Claire and the cited predicate devices.

9. Conclusions

On the basis of the information provided in this Summary, Y&J BIO Co., Ltd. believes that the easy Claire is substantially equivalent to legally commercialized predicate devices for the purposes of this 510 (k) submission.