June 22, 2020

GTG Wellness Co., Ltd.
℅ Paweena U-Thainual
CEO
MDR Solutions Co., Ltd.
1435 Kanchanapisek Rd., Bang Khae Nuea
Bangkok, Bang Khae 10160, Thailand

Re: K201107
Trade/Device Name: Opera Lebody (Gold), Opera Lebody (Zafiro)
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: April 23, 2020
Received: April 24, 2020

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,

Colin Kejing Chen
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K201107

Device Name
OPERA LEBODY

Indications for Use *(Describe)*
OPERA LEBODY is an over the counter device that is 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.

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K201107: 510(k) Summary

1. General Information

Applicant/Submitter: GTG Wellness Co., Ltd.

Address: 7, Dongwon-ro, Bundang-gu,
Seongnam-si, Gyeonggi-do,
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Tel: +82 70-4733-8244

Contact Person: Paweena U-Thainual, Ph.D.

MDR Solutions Co., Ltd.

Address: 1435 Kanchanapisek Rd.,
Bang Khae Nuea, Bang Khae,
Bangkok 10160, THAILAND
Tel: +66 2-804-2101
Email: paweena@mdrsolutions.co.th

Preparation Date: April 3rd, 2020

2. Device Name and Code

Device Trade Name: OPERA LEBODY

Common Name: OPERA LEBODY

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 Device

OPERA LEBODY is substantially equivalent to the following legally marketed predicate devices

Table 1 Predicate devices

	Primary Predicate Device	**Predicate Device**
510(K) Number	K163329	K133896
Manufacturer	Pulsaderm LLC	Trophy Skin, Inc.
Device Name	Pulsaderm Wrinkle Mask 28 and Wrinkle Mask 72	Rejuvalite MD
Model Name	Pulsaderm Wrinkle Mask 28 Pulsaderm Wrinkle Mask 72	Rejuvalite MD
Clearance Date:	April 14, 2017	November 13, 2014

4. Device Description

The OPERA LEBODY is a device which allows emission of LED light in the red (630nm) and IR (830nm) spectrum onto the face, which induces photobiological effect to the face for reduction of wrinkle. OPERA LEBODY includes the mask that contains LEDs on the inner surface, the controller which turns on and off the device, a cradle that holds the face mask, a pouch that keeps the product, and USB cable that delivers electrical power to the controller for operation or for charging the battery contained in the controller.

The user wears a mask and operates OPERA LEBODY using the controller. The device will automatically turn off after 10 minutes. Emitted light from LEDs are not intended for ocular or ophthalmic treatment. To prevent irradiation of LED lights to eyes during the treatment, OPERA LEBODY has protective eye guide which blocks light energy from LEDs.

5. Indications / Intended Use

The OPERA LEBODY is an over the counter device that is intended for the use in the treatment of full face wrinkles.

6. Technical Characteristics in Comparison to Predicate Devices

The OPERA LEBODY is substantially equivalent to the following legally marketed predicate devices

	Primary Predicate Device	**Predicate Device**	**Proposed Device**
510(K) Number	K163329	K133896	N/A
Manufacturer	Pulsaderm LLC	Trophy Skin, Inc.	GTG Wellness Co., Ltd.
Device Name	Pulsaderm Wrinkle Mask 28 and Wrinkle Mask 72	Rejuvalite MD	OPERA LEBODY
Model Name	Pulsaderm Wrinkle Mask 28 Pulsaderm Wrinkle Mask 72	Rejuvalite MD	OLG-200, OLZ-200
Clearance Date:	April 14, 2017	November 13, 2014	N/A
Product Code	OHS	OHS	OHS
Classification / Regulation	Class II	Class II	Class II
Intended Use / Indications for Use:	The Pulsaderm Wrinkle Masks 28 and 72 are intended for the use in the treatment of facial wrinkles and for people with Fitzpatrick Skin Types I, II and III	The Rejuvalite MD is an over-the-counter device intended for the use in the treatment of full-face wrinkles	OPERA LEBODY is an over the counter device that is intended for the use in the treatment of full face wrinkles.
Type of Use	Over-The-Counter use	Over-The-Counter use	Over-The-Counter use
Light Source	LEDs	LEDs	LEDs
LED emission	2 types: - Red (620~630nm) - IR (850nm)	2 types: - Red (600, 622, 660nm) - IR (860nm)	2 types: - Red (630nm) - IR (830nm)
Number of LEDs	Pulsaderm Wrinkle Mask 28: Total 28 LEDs	Total 120 LEDs	Total 78 LEDs

	Pulsaderm Wrinkle Mask 72: Total 72 LEDs		
Power Density (Irradiance)	21.18 - 25.35 mW/cm²	62 mW/cm²	50 mW/cm²
Treatment time	15 minutes every day, 60 sessions	3 minutes daily, 5 days per week for 8 weeks	10 minutes daily, 3 days per week for 8 weeks
Treatment area	Full Face	Full Face	Full Face

7. Performance Data

Non-clinical tests: Measurement of wavelength, average output power, and total irradiance of treatment LEDs were performed. Other performance, such as safety of lamps and lamp systems, electromagnetic compatibility and electrical safety, were tested using following consensus standards:

- Basic safety and essential performance of the OPERA LEBODY is tested and evaluated according to the IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007+A1:2012.
- Effect to the device by electromagnetic disturbances were tested and evaluated according to the FDA-recognized consensus standard IEC 60601-1-2 Edition 4.0 2014-02.
- Photobiological safety of lamps and lamp systems is evaluated in accordance with IEC 62471: 2006 (First Edition).
- Risk management was recorded by referring to ISO 14971: 2012.
- Usability was documented by referring to IEC 60601-1-6: 2010, AMD1: 2013.

The portion of the device that touches patient body is made of silicone and ABS plastics, which have been used for other medical devices without any biocompatibility risk.

8. Substantial Equivalence

The proposed device uses similar or identical technology as the predicate devices and has same intended uses. Based upon the predicted overall performance characteristics for the OPERA LEBODY, GTG Wellness Co., Ltd. believes that no significant differences in usage of its underlying technological principles between OPERA LEBODY and the predicate devices.

9. Conclusions

On the basis of the information provided in this Summary, GTG Wellness Co., Ltd. Believes that OPERA LEBODY is substantially equivalent to legally commercialized predicate devices for the purposes of this 510 (k) submission.