November 3, 2022

CellReturn Co., LTD.
℅ Do-Hyun Kim
CEO
BT Solutions, Inc.
Unit 904, Eonju-ro 86-gil 5, Gangnam-gu
Seoul, Seoul 06210
Korea, South

Re: K222377
Trade/Device Name: Led Mask Platinum Md
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: August 1, 2022
Received: August 5, 2022

Dear Do-Hyun Kim:

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, PhD
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)*

K222377

Device Name

LED MASK PLATINUM MD

Indications for Use *(Describe)*

LED MASK PLATINUM MD is an over the counter device that is indicated for 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.

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."

5. 510(k) Summary

5.1 General Information

Applicant/Submitter:	Cellreturn Co.,Ltd.
Address:	237, Namdongseo-ro, Namdong-gu, Incheon, Republic of Korea, 21634
Contact Person:	Do Hyun Kim, BT Solutions, Inc.
Address:	Unit 904, Eonju-ro 86gil 5, Gangnam-gu, Seoul 06210, Korea. Tel: +82-2-538-9140 Email: ceo@btsolutions.co.kr
Preparation Date:	August 4, 2022

5.2 Device Name and Code

Device Trade Name:	LED MASK PLATINUM MD
Model Name:	MQ-M21M4
Classification Name:	Light Based Over The Counter Wrinkle Reduction
Product Code:	OHS
Regulation Number:	21 CFR 878.4810
Classification:	Class II
Review Panel:	General & Plastic Surgery

5.3 Technical Characteristics in Comparison to Predicate Devices

The LED MASK PLATINUM MD, is substantially equivalent to the following legally marketed predicate devices

	Proposed Device	K180856
Company	LED Mask Platinum MD	Neutrogena Light Therapy Aging Mask+
Product name	Cellreturn Co.,Ltd.	Johnson & Johnson Consumer Inc.
Product code	OHS	OHS
Regulation number	21 CFR 878.4810	21 CFR 878.4810
Classification	Class II	Class II
Intended Use	LED MASK PLATINUM MD is an over the counter device that is indicated for the treatment of full face wrinkles.	The Neutrogena Light Therapy Aging Mask+ is an over the counter device that is indicated

		for the treatment of full face wrinkles.
Type of use	OTC	OTC
Technological characteristics		
Shape of device	Mask type	Mask type
Wavelength	630-690 nm 820-880 nm	620-640 nm 820-880 nm
Power (mW/cm2)	2	1.32
Treatment time (min)	8	10
Energy dose (J/cm2)	0.96	0.79

Irradiance of already cleared OTC device that is intended for the use in the treatment of full face wrinkles ranges from 1.32 mW/cm2 (K180856) to 62 mW/cm2 (K133896), which means irradiance that lies between these two values can be regarded as "safe" to use for the intended purpose.

5.4 Device Description

This product irradiates the skin with red light in the wavelength range of 630 to 690 nm and infrared light in the wavelength range of 820 to 880 nm. Treatment of wrinkles all over the face.

This product is designed as a portable personal medical device with a built-in battery, not a wired power supply. It is a mask-type product that is worn on the face. The operating mode of the product can be easily changed by hand. After connecting the charging adapter to the cradle, attach the main unit to the cradle to wirelessly charge the main unit with only the cradle. In addition, eye shield (for eye protection, opening/closing covers, vacuum cleaner towels, power cables, etc. are provided for convenient service use.

5.5 Indications / Intended Use

LED MASK PLATINUM MD is an over the counter device that is indicated for the treatment of full face wrinkles.

6.6 Performance Data

Non-clinical tests: Measurement of wavelength, average output power, and total irradiance (power density, in units of J/cm2) of treatment LEDs were performed. Other performance, such as safety of laser product, electromagnetic compatibility and electrical safety, etc, were tested using the following consensus standards:

- Basic safety and essential performance of the LED MASK PLATINUM MD is tested and evaluated according to the FDA-recognized consensus standard, ES 60601-1.
- Effect to the device by electromagnetic disturbances were tested and evaluated according to the FDA-recognized consensus standard IEC 60601-1-2.

- Safety of laser product is evaluated in accordance with IEC 62471, and IEC 60601-2-57.
- Risk management was recorded by referring to ISO 14971.
- Usability was documented by referring to IEC 60601-1-6.
- Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment were tested with IEC 60601-1-11.

5.7 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 LED MASK PLATINUM MD , Cellreturn Co.,Ltd.. believes that no significant differences in usage of its underlying technological principles between LED MASK PLATINUM MD and the predicate device.

5.8 Conclusions

On the basis of the information provided in this summary, Cellreturn Co.,Ltd. believes that LED MASK PLATINUM MD is substantially equivalent to legally commercialized predicate devices for the purposes of this 510 (k) submission.