December 7, 2023

Stg24 Co.,ltd.
% Do Kim
CEO
BT Solutions, Inc.
Unit 904, Eonju-ro 86-gil 5, Gangnam-gu
Seoul, 06210
Korea, South

Re: K232795
Trade/Device Name: Led Mask Platinum Exclusive 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, OLP
Dated: September 12, 2023
Received: September 12, 2023

Dear Do 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S
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Tanisha Hithe, MS, MHS
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)*

K232795

Device Name
LED Mask EXCLUSIVE MD

Indications for Use *(Describe)*
LED MASK EXCLUSIVE MD is an over the counter device that is indicated for the treatment of full face wrinkles with red light and infrared light and treat mild to moderate acne vulgaris of 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.

5. 510(k) Summary K232795

5.1 General Information

Applicant/Submitter:	STG24 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:	December 4, 2023

5.2 Device Name and Code

Device Trade Name:	LED MASK EXCLUSIVE MD
Model Name:	ME-M20M4
Common Name:	Light Based Over The Counter Wrinkle Reduction & Over-The-Counter Powered Light Based Laser For Acne
Classification Name:	Light Based Over The Counter Wrinkle Reduction & Over-The-Counter Powered Light Based Laser For Acne
Product Code:	OHS & OLP
Regulation Number:	21 CFR 878.4810
Classification:	Class II
Review Panel:	General & Plastic Surgery

5.3 Technical Characteristics in Comparison to Predicate Devices

510(k) Number	K190443
Manufacturer	Galactic Beauty, LLC
Device Name	MMSphere
Product code	OLP, OHS
Regulation number	21 CFR 878.4810
Classification	Class II

Table 5.1 Primary Predicate Devices

510(k) Number	K222377
Manufacturer	LED Mask Platinum MD
Device Name	STG24 Co., LTD
Product code	OHS
Regulation number	21 CFR 878.4810
Classification	Class II

Table 5.2 Secondary Predicate Device

The LED MASK EXCLUSIVE MD, is substantially equivalent to the following legally marketed predicate devices. K190443 is for 415nm wavelength, K22377 is for 655nm and 845nm wavelength.

	Proposed Device	K190443	K222377
Company	LED Mask EXCLUSIVE MD	Galactic Beauty, LLC	LED Mask Platinum MD
Product name	STG24 CO.,LTD.	MMSphere	STG24 Co., LTD
Product code	OLP	OLP, OHS	OHS
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Classification	Class II	Class II	Class II
Intended Use	LED MASK EXCLUSIVE MD is an over the counter device that is indicated for the treatment of full face wrinkles with red light and infrared light and treat mild to moderate acne vulgaris of the face.	MMSphereTM 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 MMSphereTM is designed to be used for 20 minute treatments three to seven times per week.	LED MASK PLATINUM MD is an over the counter device that is indicated for the treatment of full face wrinkles.
Type of use	OTC	OTC	OTC
Technological characteristics			
Shape of device	Mask type	Pannel type	Mask type
Wavelength	415 nm 655 nm 845 nm	465 nm 625 nm 605 nm	 630-690 nm 820-880 nm
Power (mW/cm2)	- Red: 1 + NIR: 1 - Blue: 1	RED:2.45 BLUE:1.33	2
Energy dose (J/cm2)	1.2	RED:2.94 BLUE:1.596	0.96

Treatment time (min)	20min/day, 120day	20min/day, 120day	8min/day
Number of LEDs	1026 ea	383 ea	684ea

Table 5.3 Comparison between the proposed device and the predicate devices

5.4 Device Description

The LED MASK EXCLUSIVE MD is an over the counter device that is intended for the treatment of full face wrinkles with red light and infrared light and mild to moderate acne with blue light. This product irradiates the skin with blue light in the wavelength range of 400 ~ 440nm, red light in the wavelength range of 630 ~ 690nm, and infrared light in the wavelength range of 820 ~ 880nm.

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 EXCLUSIVE MD is an over the counter device that is indicated for the treatment of full face wrinkles with red light and infrared light and treat mild to moderate acne vulgaris of the face.

5.6 Non-clinical test

Performance test:

- Basic safety and essential performance of the LED MASK EXCLUSIVE MD is tested and evaluated according to the FDA-recognized consensus standard, ES 60601-1.
- Photobiological safety of lamps and lamp systems is evaluated in accordance with IEC 62471:2006.
- The basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use is evaluated IEC 60601-2-57:2011.
- The basic safety and essential performance of medical electrical equipment and medical electrical systems used in the home healthcare environment is evaluated in accordance with IEC 60601-1-11:2015.
- Risk management was recorded by referring to ISO 14971.
- Usability was documented by referring to IEC 60601-1-6:2010.

Biocompatibility

- “Systemic-Acute Systemic Toxicity” and “systemic toxicity Annex G Information on material-mediated pyrogens” are evaluated in accordance with ISO 10993-11:2017.

- "I*n vitro* cytotoxicity" is evaluated in accordance with ISO 10993-5:2009.
- "Irritation and skin sensitization" is evaluated in accordance with ISO 10993-10:2010,

Software

- Software life cycle process is referred to IEC 62304:2006.
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices : FDA Guidance is referred.

EMC

- Effect to the device by electromagnetic disturbances were tested and evaluated according to the FDA-recognized consensus standard IEC 60601-1-2:2014.

Sterility and Shelf Life

- LED MASK EXCLUSIVE MD is not supplied sterile.
- The shelf life is recorded by referring to ISO 14971.

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 MMSphere, Galactic Beauty, LLC and Led Mask Platinum Md, STG24 CO.,LTD.. believes that no significant differences in usage of its underlying technological principles between LED MASK EXCLUSIVE MD and the predicate devices.

5.8 Conclusions

On the basis of the information provided in this Summary, STG24 CO.,LTD. believes that LED MASK EXCLUSIVE MD is substantially equivalent to legally commercialized predicate devices for the purposes of this 510 (k) submission.