Galactic Beauty, LLC
Ellen Marmur
President/CEO
12 E 87 St., Ste 1A
New York, New York 10128

June 24, 2019

Re: K190443
Trade/Device Name: MMSphere
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: May 28, 2019
Received: May 29, 2019

Dear Ellen Marmur:

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,

Neil R.P. Ogden, MS
Acting Assistant Director, THT4A3
DHT4A: Division of General Surgery Devices
OHT5: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

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.

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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."

510(k) Summary

MMSphere™ Light Therapy System

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR § 878.4810.

Submission Date: February 22, 2018

1. Submitter Information

Galactic Beauty, LLC
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Specification Developer

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2. General Information

2.1 Classification Name: Light Based Over The Counter Acne and Wrinkle Reduction
2.2 Common/Usual Name: Acne and Wrinkle Light Therapy System
2.3 Proprietary Names: MMSphere™
2.4 Classification: Class II
2.5 Classification Number: 878.4810
2.6 Product Code: OHS/OLP
2.7 Review Panel: General & Plastic Surgery

3. Device Description

MMSphere™ is an OTC, multi-use Light Therapy Device using LED light therapy technology for the treatment of mild to moderate wrinkles and/or acne.

The device uses a combination of red light (625nm), blue light (465nm), and amber (605nm) to create different treatment settings.

The user will wear provided goggles for treatments. Device can be used with handheld option or placed on a countertop. See Appendix: 11-1-Device Drawing and 11-3 System Level Schematic

4. Indications for Use

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.

5. Predicate Device

This device is substantially equivalent to the following predicates, which are currently cleared under product codes OHS/OLP:

1. K120775 - LightStim For Wrinkles
2. K180847 - Neutrogena Light Therapy Acne Mask+
3. K180856 - Neutrogena Light Therapy Aging Mask+

6. Comparison of Technological Characteristics with The Predicate Device

LightStim For Wrinkles K120775, Neutrogena Light Therapy Acne Mask K180847 and Neutrogena Light Therapy Aging Mask K180856 to the MMSphere™ Light Therapy System with respect to intended use, technological characteristics, principles of operation and performance data.

Device Comparison Table

	MMSphere™	Neutrogena Light Therapy Acne Mask	Neutrogena Light Therapy Aging Mask	LightStim For Wrinkles
510K Number	K190443	K180847	K180856	K120775
Product Code	OHS, OLP	OLP	OHS	OHS
Classification Name	OTC Powered Light for Wrinkle Reduction and Acne	Over the Counter powered Light Based Laser for Acne	Light-based over-the-counter wrinkle reduction	Light-based over-the-counter wrinkle reduction
Regulatory Class	Class II			
Classification Regulation	21 CFR 878.4810			
Classification Panel	General and Plastic Surgery			
Indications for Use	OTC Light Therapy Device using LED light for the treatment of wrinkles and mild to moderate acne.	The Light Therapy Acne Mask + is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.	The Neutrogena Light Therapy Aging Mask+ is an over the counter device that is indicated for the treatment of full face wrinkles.	The Light for Wrinkles is an Over-The-Counter handheld device intended for use in the treatment of full-face wrinkles.
Handheld or stationary	Both	Mask	Mask	Handheld
Irradiance Source	LEDs	LEDs	LEDs	LEDs
Light Color and Wavelengths	605nm 625nm 465nm	Red 630nm±5nm Blue 440nm±5nm	Red 620-640nm IR 820-880nm	605nm, 630nm, 660nm, 855nm
Total Energy Dose J/cm^2 *	Blue- 24.48 Red- 44	38.38	47.58	25.92
Power Density	Red 2.45 mW/cm^2 Blue 1.33 mW/cm^2	1.07 mW/cm^2	1.32 mW/cm^2	2.4 mW/cm^2
Treatment Regimen	20mins/day, 120 days	10mins/day, 60 days	10mins/day, 60 days	3mins/day, 60days

Conclusion

After an analysis of the safety indications, intended uses, performance, design materials, power output, technological characteristics, treatment areas, and treatment regimes, the Sponsor believes that no significant differences exist between the new device and the predicate devices and no new issues of safety or effectiveness are raised. Therefore substantial equivalency has been demonstrated.

7. Performance Testing

Bench performance testing was undertaken to demonstrate that the MMSphere™ is safe and effective and substantially equivalent to the predicate devices. The following are applicable consensus standards.

1. ISO 10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
2. ANSI/AAMI ES 60601-1:2005+A2 (R2012) +A1: Medical electrical equipment—Part 1: General requirements for basic safety and essential performance
3. EN 60601-1-2:2015: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
4. IEC 60601-1-6:2010+A1: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
5. 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
6. IEC 60601-2-57:2011: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
7. IEC 62133-2:2017: Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
8. IEC 62471:2006: Photobiological safety of lamps and lamp systems

8. Non-Clinical Testing

This device is in conformity with IEC 60601 electrical safety testing, IEC 60601 EMC testing and IEC 62471 photobiological safety testing.

Usability Testing

35 subjects identified with wrinkles and/or acne were given the device, the user manual and a charging cable. They were asked to turn the device on and off, change the device settings, and demonstrate how to recharge the device. After this exercise, they were asked to complete a usability survey list of 10 questions indicating how easy it was to follow instructions and use the device.

Out of 35 users participating in the Usability Study:

Addressing Usability Findings

During the course of administering the Usability Test, two specific concerns were discovered:

- The design of the knob that controls the ON and OFF positions as well as the light settings were found to be too tight to turn comfortably by the operator.
- The second concern was discovered when the operators were asked to charge the device. The access port to plug in the charging cable on the base of the device was found to be too recessed and not easily identifiable or accessible.

9. Substantial Equivalence

Based upon the analysis of the overall performance characteristics the MMSphere™ device has the same intended use as the predicate devices. The device also has similar technological characteristics to the predicate devices. The differences between the devices do not pose any safety risks to the user.

We have shown by the data contained in this 510(k) submission that the Sponsor has found no significant differences between the MMSphere™ and the predicate devices