May 14, 2023

myBlend
% José Perez
Lead Project Manager
Ceiso
69 Rue de Paris Hall B
Orsay, 91400
France

Re: K223147
Trade/Device Name: myLEDmask
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: October 5, 2022
Received: October 5, 2022

Dear José Perez:

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 -S

Jianting Wang
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)*
K223147

Device Name
myLEDmask

Indications for Use *(Describe)*
myLEDmask is an over-the-counter device that is intended to emit energy in the visible and infrared region of the spectrum for 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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PAPIER à ENTETE

510(k) SUMMARY

Prepared on ~~2022-06-06~~ 2023-04-25

1. Applicant / Submitter:

510(k) Owner	My Blend (SASU) 9 Rue du Commandant Pilot, 92200 Neuilly-sur-Seine, France Tel : +33 1 56 60 65 35

2. Submission correspondent

Contact Person	Cnnsultant	José PEREZ/ Laetitia ROBIN CEISO 69 Rue de PARIS, 91400 ORSAY Phone: +33 6 27 30 01 94 / +33 6 42 19 30 64 Email: jose.perez@ceiso.fr / laetitia.robin@ceiso.fr
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3. Device Name and Code

Device /trade Name	MyLEDMask
Classification	878.4810
Product Code	OHS : light based over the counter wrinkle reduction
Panel	General and Plastic Surgery
Class	2

4. Predicate devices

Applicant/Submitter :	LED Technologies Inc	LA LUMIERE, LLC	BioPhotas, Inc. Anaheim, CA 92805 USA	LG Electronics, Inc Gyeonggi-do, 17709, Rep. of Korea
Device Name :	DPL II PANEL	PRO X OTC 5 Light Therapy device	Biophotas Celluma3	LG PRA.L DERMA LED MASK
Product Code :	OHS	OHS	OHS	OHS
510(k)	K171390	K140471	K171323	K183671

5. Device description

MyLEDmask is a device used to perform photobiomodulation (based on light-emitting diode (LED) light) on the face and neck.

Light radiates from the inner surface of the device onto the face and neck. This light is generated by LEDs with two different visible spectrum wavelengths: red (630 nm) and near-infrared (850 nm).

3 Care programs (LEDs activation duration) based on 3 skin phototypes (skin tone) are available.

- Phototype 1 Fair Skin
- Phototype 2 Moderately Dark Skin
- Phototype 3 Dark Skin

At the end of care duration, device will automatically switch off

It is operated by a microcontroller and powered by rechargeable batteries with an external independent Charger

To prevent irradiation of LED lights to eyes during the treatment, MyLEDmask has protective eye-shield which blocks light energy from LEDs.

6. Indications for Use

MyLedMask is an over-the-counter device that is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles.

7. Summary of the technological characteristics

As described in the Product Code “OHS - Light based OTC for wrinkle reduction”, MyLEDmask principle of operation is based on generation of Red and Near infrared Light, to interact with skin, in order to reduce wrinkle, as it is long time recognized that application of low-power lights radiation in these wavelength range stimulates and enhances some cell functions.

8. Substantial Equivalence/ non-Clinical performance data:

Property	MyLedMask	DPL II PANEL	PRO X OTC 5 Light Therapy device	Celluma	LG PRA.L DERMA LED MASK
510(k) Number	Pending	K171390	K140471	K171323	K183671
Manufacturer	MyBlend	LED Technologies Inc.	LA LUMIERE, LLC	BIOPHOTAS Inc.	LG Electronics, Inc.
Device Trade name	MyLedMAsk	DPL II PANEL	PRO X OTC 5 Light Therapy device	Celluma	LG PRA.L DERMA LED MASK
Class	2				
Product Code	OHS - Light based OTC for wrinkle reduction				
Indications for Use	MyLedMask is an over-the-counter device that is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles	The dp®II Panel System is an Over The Counter (OTC) device intended for use in treating wrinkles.	The Pro X OTC 5 is an Over-The-Counter device intended for use in the treatment of facial wrinkles. It is for people with wrinkles on their face and who have	The BioPhotas Celluma3 is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles.	The LG PRA.L DERMA LED MASK is an over-the-counter device that is intended for the use in the treatment of full-face wrinkles.

Property	MyLedMask	DPL II PANEL	PRO X OTC 5 Light Therapy device	Celluma	LG PRA.L DERMA LED MASK
			Fitzpatrick skin types I, II and/or III.		
Treatment Area (cm²)	About 72 cm² estimated from the LED Mask dimension	415 cm²	Calculated at 325 cm² (Overall total Energy 332 J and Total Dose Energy 1.02 J/cm²)	Active treatment area of 15" x 8" (381 mm x 203 mm): about 77 cm²	178.8 x 225 x 89: about 50 cm² estimated from the LED Mask dimension
Materials	Mask inner face: MAKROLON 2805 Protective eye cup: Silicon TN750 Elastic band holder: Neopren and Polycotton	Not known	Not known	Not known	Mask frame: PC Eye frame: PP Eye shield: Silicone Viewing shield: ABS plastic Controller frame: PP Adaptor frame: PP Cradle frame: PP
Dimension (mm)	LED mask: 176 x 342 x 122 Storage case: 365 x 225 x 150	Not known	Not known	Not known	LED Mask: 178.8 x 225 x 89 Controller: 40 x 30 x 110 Adaptor: 87x 44 x 28 Cradle: 180 x 229 x 167.8
Net weight (g)	LED mask: 650 g Storage case: 623 g	Not known	Not known	Not known	LED Mask: 225 g / Controller: 84 g Adaptor: 75 g / Cradle: 380 g
LED Emission	Red: 630 nm (OSRAM LS T67F) NIR: 850 nm (OSRAM SFH 4253)	605 nm, 630 nm, 660 nm, 880 nm	red light (620-630nm) infrared light (855nm)	Red: 640nm+/-25nm NIR: 880nm+/-50nm	RED (637 nm) IR (854 nm)
Number of LEDs	Total 288 LEDs - 144 for 630 nm and 144 for 850 nm - 244 for the face and 44 for the neck	Not known	Not known	Not known	Total 160 LEDs (80 of them are for 637 nm and the rest 80 of them are for 854 nm)
LED Power	18.7 mW/cm² (average of 6 measurement location (including one on the neck) between 10 to 27 mW/cm²)	70.16 mW/cm²	16 mW/cm² (red) 2.9 mW/cm² (infrared) Total : 18.9 mW/cm²	6.5 mW/cm²	25 mW/cm² total
Irradiance	According to skin phototype: - 1 fair skin: 6.3 J/cm² - 2 moderately dark skin: 12.5 J /cm² - 3 dark skin: 15.6 J /cm²	12.6 J/cm² Calculated from Power (70.16 mW/cm²) and Treatment duration 3 min (180 s)	0.86 J/cm² (red) 0.16 J/cm² (infrared) Total : 1.02 J/cm²	11.7 J/cm²	13.5 J/cm² Calculated from Power (25 mW/cm²) and Treatment duration 9 min (540 s)
Treatment Time	According to skin phototype, daily - 1 fair skin: 5 min 35 (335 s) - 2 moderately dark skin: 11 min 10 (670 s) - 3 dark skin: 13 min 55 (835 s) during 6 to 8 weeks	3 minutes daily 5 days per week for 8 weeks	900 seconds per treatment 60 times	3 treatments per week (1800 seconds)- 4 weeks	9 minutes daily 5 days per week for 8 weeks
Total Energy Dose (J/cm²)	For 8 weeks, 3.5 Treatments (48 h spaced) per week: According to skin phototype: - 1 fair skin: 176 J - 2 moderately dark skin: 350 J - 3 dark skin: 437 J	For 8 weeks, 5 Treatments per week : 504 J/cm²	For 60 treatments of 900 s : 61.2 J/cm²	For 4 weeks, 3 Treatments per week : 140 J	For 8 weeks, 5 Treatments per week : 540 J
Treatment Control	Device uses a timer and software to control treatment duration. Software Safety Class: A (Low level of concern)	Not known	Not known	Device uses a timer and software to control treatment duration. Software Safety Class: A (Low level of concern)	Not known
Battery	NiMH 1.7 Ah	Not known	Not known	Not known	Lithium-ion
Power Supply	Voltage: 100 to 240 volts, AC Frequency: 50-60Hz Intensity: 0.35 A	120-240 V AC	Not known	110-120V	Input: AC 100V ~ 240V Frequency: 50Hz/60Hz Output: 5V 2A

Property	MyLedMask	DPL II PANEL	PRO X OTC 5 Light Therapy device	Celluma	LG PRA.L DERMA LED MASK
Electrical Safety	60601-2-57:2011 60601-1:2012 60601-1-2:2014	60601-1:2006 60601-1-2:2007	60601-1:2006 60601-1-2:2007 62471	60601-1:2012 60601-1-2:2007	Not known

9. Summary of the Clinical performance data

No clinical Performance data are included in this submission. However, based on FDA guidance, usability has been evaluated with panel of representative users.

10. Overall Conclusions

Comparison between device described in this 510(k) and predicate devices shows a substantial equivalence based on:

- Same Indications for Use,
- Same technological and technical characteristics (Principle of operation)
- Results of non-clinical tests

Slight differences do not raise any questions regarding safety and effectiveness.

Therefore, it can be concluded that device described in this 510(k) is « as Safe and effective »as the predicate device.