September 23, 2023

Bemer INT. AG
℅ Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr. NE
Saint Petersburg, Florida 33704

Re: K223919
Trade/Device Name: B.Light Clear Evo and B.Light Restore Evo
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: August 22, 2023
Received: August 22, 2023

Dear Paul Dryden:

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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S
2023.09.23
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Tanisha Hithe, MS, MHS
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
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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)*

K223919

Device Name

B.Light Clear Evo and B.Light Restore EVO

Indications for Use *(Describe)*

B.Light Clear Evo:
— The device is intended for over-the-counter (OTC) use to treat patients with mild to moderate acne vulgaris on the face.

B.Light Restore Evo:
— Use of light-based treatment to reduce wrinkles on the face.

Type of Use *(Select one or both, as applicable)*

__ Prescription Use (Part 21 CFR 801 Subpart D) **XX** Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date Prepared: 22-Sep-2023

I Submitter

BEMER International, AG
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LIE-9495 Triesen, Liechtenstein
Phone: +423-792-7386

Submitter Contact: Sandra Schwarzenberger
Quality Director

Submission Correspondent: Paul Dryden
ProMedic, LLC

II Device

Proprietary or Trade Name:	BEMER Therapy Systems Evo
Common/Usual Name:	Over-The-Counter Powered Light Based Laser For Acne Light Based Over The Counter Wrinkle Reduction
Classification Name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulation	(21 CFR 878.4810)
Product Code:	OHS and OLP

III Predicate Device: Shenzhen Kaiyan Medical Co. Ltd. (K202390)

Common/Usual Name:	Aduro Light Beauty Mask
Classification Name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulation	(21 CFR 878.4810)
Product Code:	OHS and OLP

Secondary Predicate Device: GlobalMed Technologies (K210948)

Common/Usual Name:	Ominlux CLEAR
Classification Name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulation	(21 CFR 878.4810)
Product Code:	OLP

Secondary Predicate Device: Johnson and Johnson Consumer (K180847)

Common/Usual Name:	Neutrogena Light Therapy Acne Mask+
Classification Name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulation	(21 CFR 878.4810)
Product Code:	OLP

Secondary Predicate Device: Cellreturn Co. Ltd (K222377)

Common/Usual Name:	LED Mask Platinum MD
Classification Name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulation	(21 CFR 878.4810)
Product Code:	OHS

IV Device Description:

The BEMER devices are noninvasive, fully reusable (no disposable components such as electrodes), and have configurations allowing both patient / home and professional / office use. The subject device is specific to the LED based applications.

Low Level Light Therapy (LLLT) delivered via Light Emitting Diodes (LED) is a nonthermal technology used to modulate cellular activity with specific wavelengths (nm) of light. Through photo biomodulation, photons are absorbed by chromophores within cells that are being treated. Various beneficial effects of LLLT delivered via light-emitting diodes at relatively low intensities have been reported, especially in indications where stimulation of healing, reduction of pain and inflammation, restoration of function, and skin rejuvenation are required. Light-emitting diode therapy (LED) is safe, nontoxic, and a noninvasive therapy for the treatment of Acne and the reduction of wrinkles and fine lines on the face.

V Indications for Use:

B.Light Clear Evo:
— The device is intended for over-the-counter (OTC) use to treat patients with mild to moderate acne vulgaris on the face.

B.Light Restore Evo:
— Use of light-based treatment to reduce wrinkles on the face.

Environments of use: OTC in the home.

VI Comparison of Technological Characteristics and Performance with the Predicate

Table 1 below provides the summarized equivalence comparison of general intended uses/actions, specific indications for use, equivalence of key clinical and technical features between subject and predicate devices, along with a full listing of technical and conformance specifications.

Table 1: Comparison of Subject vs. Predicates

	Subject Device		**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 3**	**Predicate Device 4**
Device Manufacturer	**BEMER Int. AG**	**BEMER Int. AG**	**Shenzhen Kaiyan Medical Co. Ltd.**	**GlobalMed Technologies**	**Johnson & Johnson**	**Cellreturn Co.,Ltd**
	BEMER Light Therapy System Applicator: B. Light Clear Evo	BEMER Light Therapy System Applicator: B.Light Restore Evo	Aduro Light Beauty Mask Model: MK-66O, MK-66USBO, MK-66USBA, MK-66USBB, MK-02O, MK-02A, MK-02B	Omnilux CLEAR	Neutrogena Light Therapy Acne Mask+	LED Mask Platinum MD
510(K) Number	-	-	K202390	K210948	K180847	K222377
Device Classification Name	Over the counter powered light based laser for acne	Light based over the counter wrinkle reduction	Over the counter powered light based laser for acne (OLP) Light based over the counter wrinkle Reduction (OHS)	Over the counter powered light based laser for acne vulgaris	Over the counter powered light based laser for acne vulgaris	Light based over the counter wrinkle reduction
Device Product Code	OLP	OHS	OHS, OLP, ILY	OLP	OLP	OHS
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810

	Subject Device		Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4
Indications for Use	The device is intended for over-the-counter (OTC) use to treat patients with mild to moderate acne vulgaris on the face.	Use of light based treatment to reduce wrinkles on the face.	For MK-66O, MK-66USBO, MK-02O: The Aduro Light Beauty Mask (Model: MK-66O, MK-66USBO, MK-02O) emits energy in the red and blue region of the spectrum, specifically indicated to treat full face wrinkles and/or mild to moderate acne. For MK-66USBA, MK-02A: The Aduro Light Beauty Mask (Model: MK-66USBA, MK-02A) is intended to emit light in the blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face. For MK-66USBB, MK-02B: The Aduro Light Beauty Mask (Model: MK-66USBB, MK-02B) is an over the counter device that is intended for the use in the treatment of full-face wrinkles.	Tue Omnilux CLEAR acne facemask is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris on the face.	The Neutrogena 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.	LED Mask Platinum MD is an over the counter device that is indicated for the treatment on the full face wrinkles.
Area of application	Face	Face	Face	Face	Face	Face
Wavelengths	Red: 645 nm ± 20 nm Blue: 465 nm ± 20 nm	IR: 860 nm ± 20 nm Red: 645 nm ± 20 nm	Red: 640 nm ± 10 nm Blue: 465 nm ± 10 nm	Red: 630 nm ± 5 nm Blue: 412.5 nm ± 7.5 nm	Red: 620-640 nm Blue: 425-450 nm	IR: 820 - 880 nm Red: 630 - 690 nm
Irradiance source	LEDs	LEDs	LEDs	LEDs	LEDs	LEDs
Power intensity	Red: 0.76 mW/cm² Blue: 1.20 mW/cm²	Red: 0.56 mW/cm² IR: 1.40 mW/cm²	Red+Blue: 30 mW/cm²	Red: 16 mW/cm² Blue: 28 mW/cm²	Not publicly available	IR+Red: 2 mW/cm²
Treatment dose	1 J/cm² per treatment	1 J/cm² per treatment	Not publicly available	Red: 9.5 J/cm² Blue: 16.8 J/cm²	1.28 J/cm² per treatment 38.38 J/cm² Total 30 day dose	0.96 J/cm²
Treatment time	8 minutes per day 30 days	8 minutes per day 30 days	10 minutes per day, 3 times per week	10 Minutes 4 times per week 6 weeks	10 Minutes per day 30 days	8 min each time

	Subject Device		**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 3**	**Predicate Device 4**
Total treatment time over recommended treatment period	240 minutes	240 minutes	300 minutes	240 minutes	300 minutes	Not publicly available
Power supply	Control unit : Input voltage 100 -240 V AC / 50 - 60 Hz, 15 VDC / 2A Applicator: 15 V AC	Control unit : Input voltage 100 -240 V AC / 50 - 60 Hz, 15 VDC / 2A Applicator: 15 V AC	For model MK-66O, MK-66USBO: 3.7 VDC 2600 mAh Lithium battery Adapter for charging only: Input: 100-240 VAC; Output: 5 VDC, 2A For model MK-02O: 3.7 VDC, 2600 mAh Lithium battery	Not publicly available	Batteries	Main body input power: DC 5V, 2A Built-in battery: 3.7 V, 2000 mAh
Safety and EMC	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-57
Biocompatibility	ISO 10993-1	ISO 10993-1	ISO 10993-1, ISO 10993-5, ISO 10993-10	ISO 10993-1, ISO 10993-5, ISO 10993-10	ISO 10993-1	Not publicly available
Weight	System (B.Box Evo): 926 g Applicator: 0.12 kg	System (B.Box Evo): 926 g Applicator: 0.12 kg	0.8 kg	Not publicly available	Not publicly available	Cradle: 690 g Mask: 685 g
Dimensions, Applicator (W x H x D)	12 cm x 12 cm x 2.5 cm	12 cm x 12 cm x 2.5 cm	Not publicly available	Not publicly available	Not publicly available	224 mm x 313 mm x 172 mm
Dimensions, System (W x H x D)	210 mm x 150 mm x 43 mm	210 mm x 150 mm x 43 mm	Not publicly available	Not publicly available	Not publicly available	268 mm x 183 mm x 240 mm
Power Consumption (System)	30 Watt max.	30 Watt max.	Not publicly available	Not publicly available	Not publicly available	Not publicly available

	Subject Device		**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 3**	**Predicate Device 4**
Input (System) Output (System)	100 - 240 VAC 50 - 60 Hz, 15V DC 15 V DC / 2 A Optional: Li-Ion battery	100 - 240 VAC 50 - 60 Hz, 0.6 A 15 V DC / 2 A Optional: Li-Ion battery	AC 100 - 240 V DC5V - 2.1 A Nickel metal hydride (NiMH) battery, 3.7 V, 2000 mAh.	Not publicly available	Not publicly available	AC 100 – 240 V, 50 – 60 Hz DC 5V, 2A
Number of output modes (System)	1	1	1	1	1	1
Number of output channels and ports (System)	2 for each	2 for each	1	1	1	1
Software / Firmware / Microprocessor controlled	Yes	Yes	Yes	Yes	Yes	No
Sterilization	Not provided sterile	Not provided sterile	Not provided sterile	Not provided sterile	Not provided sterile	Not provided sterile

VII Substantial Equivalence

The B.LIGHT Clear and B.LIGHT Restore applicators have the same indications for use as the predicates, K202390, K210948, K180847 and K222377.

Intended Use/ Indications for Use
The BEMER Light System can only be used with the B.BOX Evo. The BEMER devices have similar indications for use, population and use environments as the predicates K202390, K210948 and K222377 but, similar to K180847.

Technological Characteristics
The technology of the LED`s is identical to that of the predicate devices. The Power intensity (mW/cm^2) is lower than that of the predicates, K202390, K210948 and K222377.

Principles of Operation
The principle of operation is similar to the predicates, K202390, K210948, K18947 and K222377.

Non-clinical Testing
Performance testing involved multiple measurements of:

- Software
- Electrical / EMC
- Home healthcare
- Non laser-light source equipment
- Biocompatibility

Discussion of Differences
The general clinical and functional equivalence between anatomic sites and applicator use between Bemer (B. LIGHT Restore, B.LIGHT Clear) and predicate - Aduro Light Beauty Mask, Omnilux Clear and LED Mask Platinum MD.

Unlike the other devices, the BEMER Light System is controlled by an external control unit while the Predicate Devices have an integrated the controller.

This difference does not raise different risks or concerns of safety and effectiveness compared to the predicate.

VIII Conclusion

Based non-clinical performance testing and comparison to the predicates, the B.LIGHT Clear and B.LIGHT Restore have demonstrated they are substantially equivalent for safety and effectiveness to the predicate devices.