November 1, 2019

Reveallux, Corp
℅ John Gillespy
President
FDA 510k Consultants, LLC
1100 Del Lago Cir #104
Palm Beach Gardens, FL 33410

Re: K191693
Trade/Device Name: BC-5
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: GEX
Dated: June 10, 2019
Received: June 25, 2019

Dear John Gillespy:

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,

Purva Pandya
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K191693

Device Name
BC-5

Indications for Use *(Describe)*
BC-5 Red light is indicated for use in dermatology for treatment of superficial, benign vascular, and pigmented lesions.

BC-5 Blue light is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

BC-5 Red and Blue light in combination is intended to emit energy in the red and blue region of the spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

BC-5 Red and Infrared light in combination is intended to emit energy in the red and infrared region of the spectrum to treat dermatological conditions, specifically indicated to treat periorbital wrinkles.

BC-5 Infrared is intended to emit energy in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

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.

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510(k) Summary – K191693

1. 510(k) Submitter:

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Phone: 402-750-3535
Email: reveallux@gmail.com

2. Company Contact: Justin D. Linn, President

3. Date of Submission: October 31, 2019

4. 510(k) Preparer:

John F. Gillespy, MBA
FDA 510k Consulting, LLC
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Phone: 386-243-4332
Email: john@fda510kconsultants.com

5. Device Classification:

Trade name:	BC-5
Common name:	Low-Level Light Therapy Device
Device:	Powered Laser Surgical Instrument
Class:	II
Regulation #:	878.4810
Product Code:	GEX

6. Predicate:

Applicant:	Lightwave Technologies, LLC (USA)
Device:	Lightwave Professional Deluxe
510(k) Number:	K082586

7. Device Description…

BC-5 is a light-based photobiomodulation system intended for performing non-invasive, low-level light therapy (LLLT). It is used to deliver visible light wavelengths to treat dermatological conditions or to apply near infrared to the skin for topical heating.

BC-5 is a transportable, vertical system with an attached, four-panel treatment head that is manually adjusted to an appropriate distance above the patient's skin. The device does not contact the patient.

System components include a mains-powered control unit with touch-input control panel and microprocessor circuit; adjustable treatment head; and base with casters for transportability. An autolift pole connects the treatment head to the top of the main unit. An emergency stop switch allows the user to quickly shut the system down.

The technological heart of the system is RGB-IR chips (red-green-blue-near infrared). The user can select from the following five different programs, depending on type of

dermatological condition and desired electromagnetic wavelength or combination of wavelengths: red, blue, red and blue, red and infrared, and infrared. The first four are intended to treat skin conditions, while the fifth is intended for topical heating indications.

The entire system is reusable and is cleaned before each use.

The following table compares wave length and dose ranges for light emitted by the subject and predicate devices:

Table 5A

Wavelengths and Dose Ranges

Light	Wave Length (nm)		Dose Range (J/cm2)	
	Subject (±5)	**Predicate**	**Subject**	**Predicate**
Red	630	630	1-138	1-168
Blue	415	420	1-72	1-68
Infrared	835	880	1-84	1-86

8. Indications For Use…

BC-5 Red light is indicated for use in dermatology for treatment of superficial, benign vascular, and pigmented lesions.

BC-5 Blue light is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

BC-5 Red and Blue light in combination is intended to emit energy in the red and blue region of the spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

BC-5 Red and Infrared light in combination is intended to emit energy in the red and infrared region of the spectrum to treat dermatological conditions, specifically indicated to treat periorbital wrinkles.

BC-5 Infrared is intended to emit energy in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

The device is intended for prescription use only.

9. Comparison To Predicate Device…

A comparison of the subject device (BC-5) to the predicate (Lightwave) follows in Table 5B.

Table 5B - Device Comparison Table

Characteristics	Subject Device	Predicate Device	SE or Different
Name	Reveallux BC-5	Lightwave Professional Deluxe	NA
Applicant	Reveallux, Corp	Lightwave Technologies, LLC	NA
510k Number	K191693	K082586	NA
Class	II	II	SE
Regulation #	878.481	878.481	SE
Product Code	GEX	GEX	SE
Submission Type	510(k)	510(k)	SE
Common Description	LED based system using multiple wavelengths to treat multiple dermatological conditions	LED based system using multiple wavelengths to treat multiple dermatological conditions	SE
Indications For Use	BC-5 Red light is indicated for use in dermatology for treatment of superficial, benign vascular, and pigmented lesions. BC-5 Blue light is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. BC-5 Red and Blue light in combination is intended to emit energy in the red and blue region of the spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris. BC-5 Red and Infrared light in combination is intended to emit energy in the red and infrared region of the spectrum to treat dermatological conditions, specifically indicated to treat periorbital wrinkles. BC-5 Infrared is intended to emit energy in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.	The Lightwave Deluxe Red light indicated for use in dermatology for treatment of superficial, benign vascular, and pigmented lesions. The Lightwave Deluxe Red and Blue light combination is intended to emit energy in the red and blue region of the spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris. The Lightwave Deluxe Blue light is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The Lightwave Deluxe Red and Infrared light combination is intended to emit energy in the red and infra-red region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. The Lightwave Deluxe Infrared Light is intended to emit energy in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue ; and to temporarily increase local blood circulation where applied.	SE
Target Population	Individuals suffering from indicated conditions	Individuals suffering from indicated conditions	SE
Anatomical Site	Face	Face	SE
Rx/OTC/Both	Rx	Rx	SE

Physical Characteristics

System Design	Mobile workstation with hands-free mounted treatment head.	Mobile workstation with hands-free mounted treatment head.	SE
Dimensions	20in X 20in X 53in	24in X 58in	SE
Weight	110 lbs	84 lbs	SE
Energy Input	AC 85V~260V range, 50/60Hz	AC 110V or 220V, 50/60 Hz	SE
Energy Output	12w per LED; 240W per panel	Not available	SE
Technology	Photobiomodulation	Photobiomodulation	SE
Light Source	LED (nonchoherent) multi-diode	LED (nonchoherent) multi-diode	SE
Treatment Head	LED array	LED array	SE
Light Output	Red, blue, IR, red/IR, red/blue	Red, blue, IR, red/IR, red/blue	SE
Wavelength--Red	630±5nm	630nm	SE
Wavelength--Blue	415±5nm	420nm	SE
Wavelength--IR	835±5nm	880nm	See discussion
Treatment Time	Up to 20 min	Up to 20 min	SE
Intensity--Red	115 mW/cm2±10%	112 mW/cm2	SE
Intensity--Blue	60 mW/cm2±10%	45 mW/cm2	SE
Intensity--IR	70 mW/cm2	57 mW/cm2	SE
Std Dose--Red	138 J/cm2	135 J/cm2	SE
Std Dose--Blue	72 J/cm2	54 J/cm2	SE
Std Dose--IR	84 J/cm2	69 J/cm2	SE
Dose Range--Red	1-138 J/cm2	1-168 J/cm2	SE
Dose Range--Blue	1-72 J/cm2	1-68 J/cm2	SE
Dose Range--IR	1-84 J/cm2	1-86 J/cm2	SE
Wave Form	CW & Variable	CW & Variable	SE
Head/LED Configuration	All built into one head. No changing of heads	All built into one head. No changing of heads	SE
Spot Size (Coverage)	1200 cm2 (20X15X4 panels)	Up to 1662 cm2	SE
# LEDs Per Panel	60	600	SE since subject LEDs are larger with higher power (common in market now)
# Panels	4	1-3	
# LEDs Total	240	600-1800	

Components & Accessories

Vertical Console	Yes	Yes	SE
LED Panels	Yes (4)	Yes (1-3)	SE since both devices have multiple panels
Accessories	Replacement RGB-IR LED panels	RB LED panels; R-IR LED panels; RB-IR panels	SE

S&E Testing

Biocompatibility	ISO 10993-1 (no testing required as device does not touch patient)	ISO 10993-1 (no testing required as device does not touch patient)	SE
Software Validation	IEC 62304:2006 + A1:2015; SW Function Validation Tests	SW Verification & Validation	
Risk Management	EN ISO 14971:2012	ISO 14971 in SW V&V	
Electrical Safety	IEC 60601-1:2005 +C1:2006+C2:2007+A1:2012	IEC 60601-1	
EMC	IEC 60601-1-2:2014	IEC 60601-1-2	
Usability	IEC 62366-1:2015	Information not available	
Mechanical Safety	IEC 60601-2-57:2011	Temperature readings and functional tests	

There is one difference between the subject (BC-5) and predicate (Lightwave) that requires discussion:

Infrared Wavelength… The subject's central IR wavelength (835 nm) is commonly used in photobiomodulation devices, while the predicate's value (880 nm) is higher. In fact, the predicate device's own predicate (K120460) centers on 830 nm, or just slightly below the subject's wavelength.

None of the differences noted in Table 5 raise new issues of safety or effectiveness.

10. Performance Testing… BC-5 was subjected to the following non-clinical bench tests. All testing standards are currently FDA recognized, and the device passed each test:

    - EMC – EN 60601-1-2 Edition 4:2014… Medical Electrical Equipment – Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements And Tests
    - Electrical Safety – IEC 60601-1:2005, Mod… Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance
    - Risk Management – ISO 14971:2007 (Ed 2.0)… Application of Risk Management to Medical Devices
    - Software Life Cycle – IEC 62304:2015 (Ed 1.1)… Medical Device Software – Software Life Cycle Processes
    - Non-Laser Light – IEC 60601-2-57:2011 (Ed 1.0)… Non-Laser Light Source Equipment for Therapeutic.. and Cosmetic/Aesthetic Use
    - Usability Engineering – IEC 62366-1:2015… Medical Devices – Part 1: Application of Usability Engineering to Medical Devices

- Label Symbols – ISO 15223:2012… Symbols Used With Labels

11. Patient-Contacting Materials… BC-5 does not come into contact with the patient.

12. Software Verification and Validation… Software verification and validation testing were conducted in line with the requirements of FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (2005). The software for this device was considered as a "minor level of concern" and software verification and validation reports have been included in this submission.

13. Substantial Equivalence… Many of the features and technical characteristics of BC-5 (subject device) are identical to those of the Lightwave primary or GentleWaves reference devices, and where there are differences, such differences do not have an impact on the safety or effectiveness of the subject device.

    BC-5 successfully followed the pathway to Substantial Equivalence in the FDA guidance document, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications" (2014). The steps are summarized below:

    - The predicate and reference devices are legally marketed and were found substantially equivalent through 510(k) premarket submission.
    - The subject, predicate, and reference devices have the same intended use.
    - Technological differences between the subject and the predicate and reference were evaluated; none of the differences raised different issues of safety and effectiveness.
    - The following methods for evaluation of the effects of different characteristics on safety and effectiveness were deemed acceptable—testing for electrical safety, EMC, usability engineering, and non-laser light systems for therapeutic and aesthetic purposes performance; and software life cycle documentation and risk management assessment. All evaluation methods were conducted to FDA-recognized standards.
    - Data from these tests demonstrated equivalence and support the indications for use.

    In summary, all necessary testing has been performed and the results support the conclusion that BC-5 is substantially equivalent to the legally marketed predicate and reference devices based on both (a) comparison of intended use, materials, technology, and design and (b) testing to FDA-recognized standards, and the device thus does not raise any concerns of safety or effectiveness.

    Based on the information contained within this submission, it is concluded that BC-5 is substantially equivalent to the identified predicate device and warrants clearance for marketing activities.