June 20, 2024

LightFective Ltd.
% Ahava Stein
Regulatory Consultant
A. Stein - Regulatory Affairs Consulting Ltd.
18 Hata'as Str.
Kfar Saba, 4442518
Israel

Re: K233962
Trade/Device Name: ReBorn (1050nm)
Regulation Number: 21 CFR 878.5400
Regulation Name: Low level laser system for aesthetic use
Regulatory Class: Class II
Product Code: PKT
Dated: December 14, 2023
Received: December 15, 2023

Dear Ahava Stein:

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
Digitally signed by Tanisha L. Hithe -S
Date: 2024.06.20 19:17:29 -04'00'

Tanisha Hithe
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)*
K233962

Device Name
ReBorn (1050)

Indications for Use *(Describe)*
The ReBorn device is an LED technology-based system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

LIGHTFECTIVE REBORN DEVICE

510(k) Number K233962

Applicant Name:
Company Name: Lightfective Ltd.
2 Hatochen Str.
Caesarea, 3079533, Israel.
Tel: +972-54-3003187
E-mail: bahat@lightfective.com

Contact Person:
Official Correspondent: Ahava Stein
Company Name: A. Stein – Regulatory Affairs Consulting Ltd.
Address: 18 Hata'as Str., Suite 21
Kfar Saba 4442520 Israel
Tel: + 972-9-7670002
Fax: +972-9-7668534
E-mail: ahava@asteinrac.com

Date Prepared: April 10, 2024

Trade Name: ReBorn

Classification Name: CFR Classification section 878.5400; (Product Code PKT)

Classification: Class II Medical Device

Predicate Device:

The ReBorn device is substantially equivalent to the following predicate device:

Manufacturer	Device Predicate	510(k) No.
Venus Concept Ltd.	Venus Bliss	K190743

Device Description:

The ReBorn system is a non-invasive, LED-based system intended for non-invasive lipolysis and indicated for non-invasive lipolysis of the abdomen and flanks.

The Lightfective ReBorn System is a Light Emitting Diode (LED) system, generating optical energy at 1050nm. The ReBorn's cooling and electrical systems maintain safe and comfortable skin surface temperatures. The Lightfective ReBorn system delivers power of up to 49 Watts (per each applicator) in continuous wave (CW) mode. The device consists of hardware and software. These elements are integrated in the ReBorn console and applicator/handpiece. The ReBorn system is supplied as a console and 4 identical applicators. The device is portable and was specifically designed to be utilized in clinic environments.

The console is floor-standing and portable. It is controlled by a touch screen and consists of the following subsystems:

- Power Supply
- Main Controller unit (CPU)
- Water cooling system (Chiller)
- Touchscreen display monitor
- System on Module (SOM) and proprietary software
- Applicator docking panel (cradle)
- Four designated applicator connector ports

Intended Use/Indication for Use:

The ReBorn device is an LED technology-based system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less.

Performance Standards:

The ReBorn device complies with the following FDA recognized consensus standards:

- IEC 60601-2-57 Edition 1.0 2011-01 Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements forbasic safety and essential performance

- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices
- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices
- Part 10: Tests for irritation and skin sensitization
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
- ISO 14971 Medical devices - Application of risk management to medical devices

Non-Clinical (Bench) Performance Data:

Following is a description of the non-clinical performance tests performed on the device and provided in the 510(k) submission:

- Temperature Control Test - evaluated the accuracy of the ReBorn temperature sensors, by comparing the temperature measured by the temperature sensors of the ReBorn device to calibrated thermocouples.
- Cooling Capacity Test - evaluated the cooling capacity of the system's cooling unit during various types of treatments and verified that the cooling temperature remains within the predetermined range at all times.
- Applicator Power Performance Test - verified that the deviation between the user-set power and the actual power output from the applicator falls within the permitted range.
- Applicator Contact Sensor Test - tested the functionality of the contact sensors in multiple scenarios and demonstrated the proper display of the sensor indicator lights according to the device functionality.
- Lifetime Rationale - the expected life time or operational life of the ReBorn device and the applicator were evaluated.
- Ex-vivo Animal Study - evaluated the thermal effect of the ReBorn device on porcine abdominal skin and adipose tissue and demonstrated substantial equivalence to the FDA-cleared, predicate device, i.e., the Venus Bliss™.

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The ReBorn system is substantially equivalent to the Venus Bliss device (Venus Concepts USA Inc.) cleared by FDA in 510(k) K190743.

Table 1: Comparison of the ReBorn Device to the predicate Venus Bliss device (K190743)

Characteristic	**Subject Device ReBorn (Lightfective Ltd.)**	**Predicate Device Venus Bliss (Venus Concepts USA Inc., K190743)**
Device Classification, Indication for Use, Intended Use		
Device Classification	Class II	Class II
Classification Panel	General and Plastic Surgery	General and Plastic Surgery
Classification Product Code	PKT	PKT
Regulation Number	878.5400	878.5400
Indications For Use	The ReBorn System is a LED system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less.	The Venus Bliss device is a diode laser system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less.
Target Population	Adult subjects	Adult subjects
Anatomical Sites	Abdomen and flanks	Abdomen and flanks
Environment Used	Clinic	Clinic
Technological Characteristics		
Device Description	The ReBorn is a Light Emitting Diode (LED) system delivering optical energy, which can disrupt adipocyte cells to provide a non-invasive approach to achieve a desired aesthetic effect. The ReBorn system is specifically indicated for treatment of the abdomen and flanks.	The Venus Bliss device is a diode laser system delivering optical energy, which can disrupt adipocyte cells to provide a non-invasive approach to achieve a desired aesthetic effect. The Venus Bliss is specifically indicated for treatment of the abdomen and flanks.
Device Components	• Power supply unit • Controller unit • Cooling system • Touchscreen display monitor • PC and proprietary software • 4 Applicators • Applicator belt	• Power supply unit • Controller unit • Cooling System • Touchscreen display monitor • PC and proprietary software • 4 Applicators • Applicator belt
Energy Source	Light Emitting Diode (LED)	Diode Laser
Mechanism for Heat Generation	An array of LED's delivering optical energy	Diode laser delivering optical energy
Wavelength	1050 nm $\pm$ 20 nm	1064 nm $\pm$ 10 nm
Spot Size	35cm^2 (5x7cm)	36cm^2 (6 x 6 cm)

Characteristic	Subject Device ReBorn (Lightfective Ltd.)	Predicate Device Venus Bliss (Venus Concepts USA Inc., K190743)
Pulse Width (laser ON time)	CW	CW
Maximum Power Density	1.4 W/cm^2	1.4 W/cm^2
Attachment to Patient	Applicator Belt	Applicator Belt
Duration of Treatment	25 minutes of treatment	25 minutes of treatment
Treatment Temperature: **Adipose Tissue** **Skin**	 42-47°C 14°C	 42-47°C 14°C
Temperature regulation	Temperature at the applicator is continuously monitored to ensure it does not exceed the maximum allowable temperature.	Temperature at the applicator is continuously monitored to ensure it does not exceed the maximum allowable temperature.
Cooling System	Water based	Water based
Rate of Heating (time to reach target temp)	4 minutes	~5 minutes
Power supply	AC/DC power: 50-60 Hz 120-240VAC 12A Single phase	AC/DC power: 50-60 Hz 100-240VAC <10A Single phase
Dimensions	35cm(W) x 52.5cm(D) x131.5cm(H) 13.75"(W) x 20.75"(D) x 51.75"(H)	55cm(W) x 65cm(D) x 135cm(H) 21.7"(W) x 25.6"(D) x 53.2"(H)
Weight	50 kg (110 lbs)	62 kg (137 lbs)
Sterilization	The ReBorn system is non-sterile	The Venus Bliss device is non-sterile
Single Use or Reusable	ReBorn system: reusable Applicators: reusable	Venus Bliss device: reusable Applicators: reusable
Performance Testing		
Biocompatible patient-contacting materials (ISO 10993-1)	Yes, medical-grade materials	Yes, medical-grade materials
Thermal Safety	Bench testing verified thermal safety requirements	Information not available
Software	Testing was performed to validate that the software met all requirements	Testing was performed to validate that the software met allrequirements
Electrical Safety per IEC 60601-1	Meets requirements	Meets requirements
Electromagnetic Compatibility (EMC) per IEC 60601-1-2	Meets requirements	Meets requirements

Conclusions:

The ReBorn system has the same intended use and indication for use as the Venus Bliss device and the technological characteristics are similar or even identical, including similar device components (i.e., power supply, control unit, water-based cooling system, operator interface and display monitor, software and applicators), similar mechanism of action (heating tissue using optical energy to achieve adipose tissue disruption and thus achieve lipolysis of the abdomen and flanks), similar treatment administration, similar energy regulation methods, biocompatible materials, validation of software component, and similar compliance with electrical, EMD and optical energy emitting device standards. The most important technological characteristic, i.e., using optical energy to deliver heat to the body area to induce the adipose tissue disruption for lipolysis of the abdomen and flanks, is the same in both devices.

The minor difference between the devices in the optical energy delivery elements (light emitting diode vs laser diodes) and configuration of the spot size does not raise new types of questions about safety and effectiveness. That is, the questions regarding the safety and effectiveness of the optical energy output in the Reborn system are the same questions that were asked of the predicate, Venus Bliss device. Furthermore, there are acceptable scientific methods to evaluate these aspects of the device, including compliance with FDA recognized methods and standards to demonstrate optical safety and testing to validate the generated optical energy output in the ReBorn system is at least as safe and effective as the legally marketed, predicate Venus Bliss device. The compliance with standards information is provided in Section 8 (Software Validation), and Section 9 (Electrical and EMD) and Section 5 provides the Performance Testing in this 510(k) submission.

Consequently, the safety and effectiveness information provided in the 510(k) submission performance testing sections (hence, sections 5, 8, and 9) provide the supportive data necessary to demonstrate that the ReBorn system is substantially equivalent to the predicate Venus Bliss device (FDA-Cleared under 510(k) K190743).