



Food and Drug Administration  
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February 24, 2016

Centre Light Solutions, LLC  
% Ms. Audrey Swearingen  
Emergo Global Consulting, LLC  
816 Congress Avenue, Suite 1400  
August, Texas 78701

Re: K151337

Trade/Device Name: Strialite  
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: ONE  
Dated: January 8, 2016  
Received: January 12, 2016

Dear Ms. Swearingen:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Jennifer R. Stevenson -S**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151337

Device Name

Strialite

Indications for Use (Describe)

Strialite is an over-the-counter device indicated for use in the temporary reduction of redness in striae rubra (red stretch marks). Strialite does not remove the stretch marks but may improve their appearance

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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## 510(k) Summary for Strialite™

### 1. Submission Sponsor

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### 2. Submission Correspondent

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### 3. Date Prepared

February 19, 2016

### 4. Device Identification

Trade/Proprietary Name: Strialite™  
Common/Usual Name: Light Emitting Diode (LED) device  
Classification Name: Laser surgical instrument for use in general and plastic surgery  
and in dermatology.  
Classification Regulation: 21 CFR 878.4810  
Product Code: ONE  
Device Class: Class II  
Classification Panel: General and Plastic Surgery

### 5. Legally Marketed Predicate Device(s)

Candela V Beam Pulse Dye Laser System, K013748

## 6. Device Description

The Strialite is an over the counter (OTC) device utilizing a combination of light emitting diode (LED) lights and a heating element as a phototherapy/thermal treatment for the end users' stretch marks (striae). It is a hand-held, compact, lightweight device, designed to specifically treat and reduce the visible appearance of an individual's red stretch marks. A stretch mark is a defect in the skin caused by damaged collagen that occurs from rapid skin stretching, that may have a red appearance. The red LED light and heat work together to stimulate the skin at the cellular level to produce and repair collagen. As the damaged collagen tissue is gradually replaced, over time the appearance of the stretch mark is reduced. Typical areas for treatment are the abdomen, breasts, back, hips, and thighs. The recommended treatment schedule is two (2) 20-minute sessions a week for at least four (4) weeks. Strialite is intended for home use by adults under the age of 50 years.

The Strialite device consists of a housing enclosure with an ergonomic handle, electronic circuit boards, treatment plate with a specific array of LED lights, thermal heating elements that generate temperature up to 105 degree F (40 degree C), touch control power button (On/Off), and a power cord. The flat LED panel, consisting of thirty-five (35) visible red LEDs in the 633 nm ( $\pm 5$ nm) spectrum, is located on the base of the device, and directly contacts the area of skin to be treated. The device is provided non-sterile and reusable.

## 7. Indications for Use Statement

Strialite is an over-the-counter device indicated for use in the temporary reduction of redness in striae rubra (red stretch marks). Strialite does not remove the stretch marks but may improve their appearance.

## 8. Substantial Equivalence Discussion

As shown in **Table 5A** below, Strialite has the same intended use and similar technological characteristics and principles of operation as the predicate device, the Candela V Beam, and therefore is substantial equivalent to the predicate device.

**Table 5A – Comparison of Characteristics**

Manufacturer	Centre Light Solutions	Candela Corporation	Comparison of Significant Differences
Trade Name	Strialite	Candela V Beam Pulse Dye Laser System	
510(k) Number	N/A	K013748	N/A
Product Code	ONE	ONE	Same
Regulation Number	878.4810	878.4810	Same
Regulation Name	Laser surgical instrument for use in general and plastic surgery and in dermatology	Laser surgical instrument for use in general and plastic surgery and in dermatology	Same
Intended Use	Over the counter light device for use in dermatology	Prescription light device for use in dermatology	Strialite is for OTC use, which is supported by the usability and self-selection studies, and clinical data.

Manufacturer	Centre Light Solutions	Candela Corporation	Comparison of Significant Differences
Trade Name	Strialite	Candela V Beam Pulse Dye Laser System	
Indications for Use	An over the counter device indicated for use in the temporary reduction of redness in striae rubra. Strialite does not remove the stretch marks but may improve their appearance.	A prescription device indicated for use in dermatology for the treatment of striae.	The fundamental technology and the intended use to treat stria rubra using and heat and red light are the same.
Hand-Held	Yes	Yes	Same
Patient Contact Materials	Anodized aluminum Plastic	Stainless steel Plastic	Both devices utilize materials commonly used in medical devices having limited skin contact.
Sterile	No	No	Same
Single-Use	No	No	Same
Peak Emission Wavelength	633 ± 5nm	595 ± 5nm	Both devices utilize light in the red spectrum.
Mechanism of Action	Red light energy and dermal heating increases local circulation and collagen production	Red light energy and dermal heating increases local circulation and collagen production	Both devices use a combination of red light energy and heat
Software	No	Yes	To keep the user functions simple, no software is used in the Strialite.
Recommended Operating Conditions	Room temperature	Room temperature	Both operate within normal room temperatures
Electrical Safety / EMC Testing Passed	Yes	Yes	Same
Clinical Study	Yes	unknown	Strialite has been shown to be safe and effective for its intended use.

## 9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Strialite and to show substantial equivalence to the predicate device, Centre Light Solutions completed a number of tests. The Strialite passed all testing stated in **Table 5B** below as shown by the acceptable results obtained. These tests confirm that the output meets the design inputs and specifications and support Strialite's safety, performance and substantial equivalence to the predicate device.

**Table 5B – Summary of Non-clinical Performance Testing**

Testing Type	Test Performed / Standard	Result
Design Verification	Strialite Over-Temperature Sensor Verification Study	The Strialite shuts off when the plate temperature exceeds 41 °C.
	Strialite Power Switch Reliability Verification	The power switch of the device successfully performed 500 ON/OFF cycles.
	Strialite Overtemperature Sensor with Runaway Resistors	In a single fault failure mode, the over-temperature protection sensor shut-off the heat well before the treatment plate reached a hazardous temperature (<51°C).
	Strialite Use Life – LED Specification	The LEDs exceeded the specification of 1000 hours of continuous use.
	Strialite Temperature Verification	The temperature of the treatment plate met the specification at 1 minute and at 20 minutes after the device is turned on. The device operated successfully within the specified environmental temperature for the stated time period.
Electrical Safety	AAMI ES60601-1:2005/A1:2012 (Ed. 3.1) - Medical electrical equipment Part 1: General requirements for basic safety and essential performance	Strialite complies with the stated performance standard for electrical safety for medical equipment used in a home healthcare environment.
	IEC 60601-1-11: 2010, first ed. - Medical electrical equipment Part 1-2: 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	
	IEC 60601-2-57: 2011 - Medical electrical equipment Part 2-57: particular requirements for basic safety and essential performance on non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use	
Electromagnetic Compatibility	IEC 60601-1-2: 2007, 3rd ed. - Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic Compatibility	Strialite complies with the stated performance standard for EMC.
Photobiological Safety	IEC 62471: 2006, first ed. - Photobiological safety of lamps and lamp systems	Strialite complies with the stated performance standard for photobiological safety.
Biocompatibility	ISO 10993-1:2009 – Biological Evaluation of Medical Devices-Part 1: Evaluation and testing within a risk management system	Strialite complies with the standard and was determined to be biocompatible for its intended use.

## 10. Clinical Performance Data

A clinical study was conducted to assess the effect of Strialite on the temporary reduction of redness of the subjects' red stretch marks. Thirty of the 33 subjects enrolled completed the full series of 8 treatments over 4 weeks. Sixteen out of 30 subjects reported, upon self-assessment, improvement of the severity of the redness of their stretch marks of at least 2 grades when graded on a scale of 1 to 10 from baseline to post-treatment. As a secondary endpoint blinded photographic assessment was performed and the blinded evaluation identified 18 of the 30 subjects as demonstrating improvement. Two subjects that self-assessed as having the worst appearing lesions (grade 10) did not show any improvement throughout the study. No adverse effects were observed or reported during the study.

As the Strialite is for OTC use, a usability study, designed in accordance with AAMI ANSI IEC 62366:2007, assessed whether subjects, after reading the labeling provided with the Strialite, were able to properly use the device without assistance. The usability test consisted of two components:

- 1) Demonstrating the ability to read and comprehend the information in the Instructions for Use and Quick Start Guide, based on survey questions asked by an interviewer.
- 2) Demonstrating correct simulated use of the device by following the Instructions for Use and Quick Start Guide, as observed and recorded by the trained interviewer.

The study showed that 39 of 40 (97.5%) subjects were able to read and comprehend the information in the Instructions for Use manual, and that 38 of 40 (95.0%) subjects were able to correctly demonstrate the six critical steps in the use of the Strialite.

In addition, a Self-selection study was performed with forty-one (41) subjects who were each given the device carton labeling to read in private. When interviewed, all responders correctly determined from the carton labeling that the device is used for stretch marks, and all but one correctly self-selected.

## 11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when it has the same intended use and the same technological characteristics as the previously cleared predicate device; or the device has the same intended use and different technological characteristics, but it can be demonstrated that the differences do not raise different questions regarding its safety and effectiveness as compared to the predicate device.

Strialite is substantially equivalent to the predicate device, Candela V Beam Pulse Dye Laser, in that they both have the same intended use and share similar technological characteristics and principles of operation. Both devices are intended for the same use which is the treatment of striae rubra (red stretch marks) by combining heat and light to reduce the redness of the stretch mark. It has been shown in this 510(k) submission that the differences between the Strialite and the Candela V Beam predicate device do not raise new questions regarding Strialite's safety and effectiveness. The Strialite is determined to be substantially equivalent to the predicate device.