December 14, 2021

Lightsense Technologies Ltd
℅ John Smith
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K202848
Trade/Device Name: S2 Pigment Removal System
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: November 1, 2021
Received: November 1, 2021

Dear John Smith:

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 and Part 809); 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
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)*

K202848

Device Name

S2 Pigment Removal System

Indications for Use *(Describe)*

S2 Pigment Removal System is intended for use in removal of tattoo ink. The S2 Pigment Removal System is indicated for the removal of tattoo ink according to the following wavelengths:

800 nm:

The LightSense S2 800 nm Ti:Sapphire laser system is indicated for tattoo removal for Fitzpatrick Skin Types I-III.

532 nm:

The LightSense S2 532 nm Nd-YAG laser system is indicated for tattoo removal for Fitzpatrick Skin Types I - III.

1064 nm:

The LightSense S2 1064 nm Nd-YAG laser system is indicated for tattoo removal for Fitzpatrick Skin Types I-VI.

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

X 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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510(k) SUMMARY

LIGHTSENSE TECHNOLOGIES LTD's S2 Pigment Removal System

K202848

Submitter

LIGHTSENSE TECHNOLOGIES LTD
109 Great Portland Street
London
W1W 6QG
United Kingdom

Phone: +44 20 7031 3471

Contact Person: Dr. Deganit Barak

Date Prepared: December 13, 2021

Name of Device: S2 Pigment Removal System

Common or Usual Name: Powered Laser Surgical Instrument

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: Class II

Product Code: GEX

Predicate Devices: Cynosure, PicoSure Workstation (K160480)

Device Description:

The S2 Pigment Removal Laser System (S2) uses high intensity laser pulses to remove tattoo ink from skin. The S2 includes the two treatment lasers, an aiming beam, a small galvanometric scanner, an articulating arm, a hand-piece with an adjustable spacer, and a foot pedal. The S2 uses two lasers to deliver three working wavelengths: (1) 800nm, ultra-short pulsed Ti:Sapphire laser, and (2) 1064 and 532nm Nd:YAG short pulse laser. The combined lasers are designed to remove tattoos.

Intended Use / Indications for Use

S2 Pigment Removal System is intended for use in removal of tattoo ink. The S2 Pigment Removal System is indicated for the removal of tattoo ink according to the following wavelengths:

800 nm:

The LightSense S2 800 nm Ti:Sapphire laser system is indicated for tattoo removal for Fitzpatrick Skin Types I-III.

532 nm:

The LightSense S2 532 nm Nd-YAG laser system is indicated for tattoo removal for Fitzpatrick Skin Types I - III.

1064 nm:

The LightSense S2 1064 nm Nd-YAG laser system is indicated for tattoo removal for Fitzpatrick Skin Types I-VI.

Summary of Technological Characteristics:

Laser energy emitted at different wavelengths is the technological principle for both the subject and predicate devices. At a high level, the subject and predicate devices are based on the following same technological elements:

Both systems include multiple lasers which operate at comparable wavelengths, allowing the operator to select the best wavelength for the patient based on the color of the tattoo which the patient wishes to have removed. The laser systems also both have treatment hand-pieces connected to articulated arms that are connected to the main console where the user interface is located. The following technological differences exist between the subject and predicate devices:

A table comparing the key features of the subject and predicate devices is provided below.

	S2 Pigment Removal System		**PicoSure™**	
Components	Laser systems, three wavelengths, treatment hand pieces, articulated arms, main console, user interface, switch pedal		Laser systems, three wavelengths, treatment hand pieces, articulated arms, main console, user interface, switch pedal	
Accessories	Spacer (connected to the treatment hand piece)		interchangeable handpieces including spacers and treatment tips	
Power Source	100-240V, 50-60Hz		200-240V, 50/60Hz	
	Nd:YAG	Ti:Sapph	Nd:YVO4	Alexandrite
Wavelength (nm)	1064, 532	800	1064,532	755
pulse energy (mJ)	1-8 mJ	1-5 mJ	450	450
pulse width (ps_	400-700	8	450-900	450-900
spot size (diam)/ treatment field (mm)	0.4–1 / 1-10	0.4–1 / 1-10	4	3
pulse repetition rate (Hz)	500	1000	1-10	1-10

Fluence (J/cm^2)	0.5-8 J/cm^2	0.5–4 J/cm^2	3.6/1.5	6.4
Safety Features	Emergency stop button, Door interlock, Emission Indication LED, Outline Mode Before Lasing, Outline Scan, Motion Sensor, Spacer Feedback, Realtime Monitor, Built-in test		Key Switch, Emergency laser stop, Standby Mode, Delayed Ready Mode, Automatic Shutdown Feature, Remote Interlock, Audible Tone, Laser Danger Sign, Locking Casters, Device Labels	
Biocompatibility	Yes (spacer)		Yes (treatment tip)	
Software	Yes		Yes	
Sterilization	No (Cleaning and disinfection of the spacer)		Cleaning and disinfection of the treatment tip, following by autoclave sterilization	
Standards with which the Device Complies	IEC 60601-1, IEC 60601-2, ANSI Z-136. 3; CFR Part 1000 [parts 1040.10 and 1040.11]; 12-273 IEC 60825-1 Edition 2.0 2007-03		IEC 60601-1, IEC 60601-2, ANSI Z-136. 3; CFR Part 1000 [parts 1040.10 and 1040.11]; 12-273 IEC 60825-1 Edition 2.0 2007-03	

Performance Data

Safety and performance data demonstrates that the S2 Pigment Removal System complies with the following FDA recognized consensus standards:

- AAMI/ANSI ES60601-1:2005(R) 2012 and A1:2012 Electrical safety
- IEC 60601-1-2:2014 Electromagnetic compatibility including radiated emissions and immunity
- IEC 60601-1-6:2010 General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-22: 2007 (Third Edition) + A1:2012 Essential performance and safety for laser products
- IEC 60825-1:2014 Safety of laser products
- ISO 10993-5:2009 and ISO 10993-10:2010 Biocompatibility to address cytotoxicity, sensitization, and irritation of skin contacting components

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" consistent with "moderate" level of concern. Each element of the SRS was tested and found to meet the requirements.

In addition, bench testing was performed to address verification of the device output parameters, including wavelength and fluence transmission. Moreover, two animal preclinical studies were conducted. One study was conducted to validate findings from the bench testing and to confirm optimal parameters for tattoo removal. The other study was conducted to establish optimal treatment protocols. In all instances, the S2 Pigment Removal System functioned as intended and consistent with the predicate device.

A clinical study was conducted in 58 subjects with colored tattoos and various skin types (Fitzpatrick I-IV) and at various depths within the skin. Subjects received a maximum number of 16 treatments, where a maximum of 2 treatments were applied at each study visit, spaced 2 weeks apart. Treatments were conducted with the three wavelengths, using the specific wavelength relevant to the specific tattoo color, in order to validate the safety and efficacy of the tattoo removal by the device. Some subjects were treated by more than one laser wavelength depending on the coloration of the tattoo. The study primary endpoint was an evaluation of tattoo clearing as rated by a panel of blinded reviewers based on a photographic assessment performed 8 weeks post-final treatment based on a 5 point global assessment scale.

The primary and secondary endpoints were both reached successfully in terms of efficacy and safety. No serious adverse device effects were reported and the few minor observed adverse effects (AE) were minor with no observed long-term effects.

Analyzing the clearing of tattoos at the 8 week follow up visit after the final treatment session, when analyzed by tattoo color segment, results show 100% percent of subjects in the analysis population with tattoo clearance of more than 50% compared with baseline photographs. Results by wavelength show 100% responders regardless of the wavelength used during treatment.
The safety and performance of the device is further supported by real world data gathered in commercial clinical practice. Data from a total of 957 patients undergoing treatment with the device for tattoo removal support the device safety and performance across wavelengths, tattoo colors, and skin types.

In addition to the data discuss above from the clinical study,136 patients have been treated with the 532nm wavelength for the clearance of tattoos with red, yellow and orange ink. Tattoo clearance using 532nm has shown to achieve equivalent or better clearance by session compared to the 1064nm laser wavelength for the removal black ink. Other less-common colors have similarly obtained favorable results. Specifically, purple ink treated with 800nm (n=13) has obtained greater than 50% clearance (as assessed immediately following treatment) in fewer treatments than was necessary to obtain the same level of clearance for red, yellow, orange inks or black ink.

For persons with darker skin types (Fitzpatrick V and Fitzpatrick VI), data from 109 patients from commercial clinical use supports the safety and performance of the 1064nm laser wavelength using a modified treatment protocol with additional time between treatment sessions. Efficacy is comparable for all patients removing black ink with the 1064nm laser wavelength, regardless of skin type. The available real world data shows a lower overall incidence rate of post-treatment reactions in Fitzpatrick V and VI patients (7.34%) than Fitzpatrick I-IV patients (9.67%). Regarding the classification of these in-treatment reactions; persons with darker skin tones are more likely to observe temporary swelling (73.1%) and less likely to observe redness (79.5%) when compared to Fitzpatrick 1-4 patient groups.

Based on the clinical performance as documented in the pivotal clinical study and the real world data collection, the S2 Pigment Removal System has a safety and effectiveness profile that is similar to the predicate device.

Conclusions:

The S2 Pigment Removal System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended therapeutic use of the device and do not alter its safety or effectiveness when used as instructed in the product labeling. In addition, the minor technological differences between the S2 Pigment Removal System and its predicate device raise no new issues of safety or effectiveness. Moreover, performance data, animal data, and clinical study data demonstrate that the S2 Pigment Removal System is as safe and effective as the PicoSure predicate device.