LUVO Medical Technologies, Inc
Mr. Gregory Berzak
Regulatory Affairs Officer
125 Fleming Dr.
Cambridge, CA N1T 288 Ontario

March 10, 2020

Re: K193446
Trade/Device Name: Bare: 808
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: December 6, 2019
Received: December 12, 2019

Dear Gregory Berzak:

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,

Neil R.P. Ogden, MS
Assistant Director, THT4A4
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)*
K193446

Device Name
Bare: D808 Laser System

Indications for Use *(Describe)*

The hair removal single (HRS) and hair removal moving (HRM) mode are intended for permanent reduction in hair regrowth defined as long term, stable reduction in the number of hairs re-growing when measured at 6,9, and 12 months after the completion of a treatment regimen.
Use on all skin types (Fitzpatrick I-VI) including tanned skin

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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Attachment 5
510(K) Summary
Bare : 808 Laser System (K193446)

This 510(K) Summary of safety and effectiveness for the Bare : 808 Laser System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	LUVO Medical Technologies, Inc.
Address:	LUVO Medical Technologies, Inc. 125 Fleming Dr Cambridge, Ontario, Canada N1T 2B8
Contact Person:	Mr. Gregory Berzak
Telephone:	519-6203900– phone gregoryb@clarionmedical.com
Preparation Date:	December 6, 2019
Device Trade Name:	Bare : 808
Common Name:	Powered laser surgical instrument
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and dermatology
Regulation Number:	21 CFR 878.4810 (Product Code: GEX)
Legally Marketed Predicate Devices:	Soprano XL Family of Multi-application and Multi-technology Platform
510(K) number:	(K)140009 (K)170626 (Reference Only)
Regulatory Class:	Class II Prescription Use
Description of the Bare : 808 Laser System:	The Bare : 808 Laser is a microprocessor-controlled, user friendly, sealed diode laser system that produces a wavelength of 808nm with a maximum energy of 120Jcm2. The system incorporates a diode laser within each hand piece, and the energy is delivered from the hand piece directly to the desired target. The Bare: 808 Laser consists of a console, a touch screen user interface, a footswitch and 1 handpiece.
Intended use / Indication for use of Bare : 808 Laser System	The hair removal single (HRS) and hair removal moving (HRM) modes are intended for permanent reduction in hair regrowth defined as long term, stable reduction in the number of hairs re-growing when measured at 6,9, and 12 months after the completion of a treatment regimen. Use on all skin types (Fitzpatrick I-VI) including tanned skin.

Performance Data:

The following performance data was provided in support of the substantial equivalence determination:

IEC 60601-1:2005 (Third Edition) + CORR.1:2006 + CORR.2:2007 + A1:2012 (or IEC 60601-1:2012 reprint): Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance.

IEC 60601-1-2:2014, EN 60601-1-2:2015 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility

IEC 60601-2-22:2007 + A1:2012: Test for Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

Results of Clinical Study:

A human clinical study was not required as the device is substantially equivalent to the predicate devices.

Technical Specifications / Indications for Use Comparison:

	Bare: D808 (K193446)	Soprano Ice (K140009)
Intended Use	The device is intended for use in dermatologic and general surgical procedures	The device is intended for use in dermatologic and general surgical procedures
Indication for Use	The hair removal single (HRS) and hair removal moving (HRM) modes are intended for permanent reduction in hair regrowth defined as long term, stable reduction in the number of hairs re-growing when measured at 6,9, and 12 months after the completion of a treatment regimen. Use on all skin types (Fitzpatrick I-VI) including tanned skin.	The hair removal (HR) and super hair removal (SHR) mode are intended for permanent reduction in hair regrowth defined as long term, stable reduction in the number of hairs re-growing when measured at 6,9, and 12 months after the completion of a treatment regimen. Use on all skin types (Fitzpatrick I-VI) including tanned skin.

Attachment 5
510(K) Summary
Bare : 808 Laser System (K193446)

Characteristic	**Bare : 808 (K193446)**		**Soprano Ice (K140009)****	
Wavelength (nm)	808		810	
Laser Media	Solid State		Solid State	
Modes	HRS	HRM	HR	SHR
Energy Density (Fluence)	2-120	2-20	2-120	2-20
Spot Size (mm)	14 x 14	14 x 14	12 x 10	20 x 10
Pulse Width (msec)	15-400	15-266	5-200	5-200
Repetition Rate (Hz)	3-10		3-10	
Delivery Devices	Nonsterile, Reusable, cleanable		Nonsterile, Reusable, cleanable	

** The Soprano Ice (K140009) has additional wavelengths and specifications that have not been included as part of this submission. The comparison of the Bare: 808 and the Soprano Ice are for the diode hair removal module only.

Conclusion: The Bare : 808's intended use, indications for use and technical specifications are substantially equivalent to the predicate device.