DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 13, 2015

Shaser Incorporated
Mr. Anthony Burns
Senior Director of Regulatory Affairs
10 Maguire Road
Lexington, Massachusetts 02421

Re: K142924
Trade/Device Name: Shaser Skin Beauty SkinREJUV Intense Pulsed Light System Family
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 4, 2014
Received: December 5, 2014

Dear Mr. Burns:

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" (21CFR 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

ATTACHMENT 2

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)*
K142924

Device Name
Shaser Skin Beauty SkinREJUV Intense Pulsed Light System Family

Indications for Use *(Describe)*
Shaser Skin Beauty SkinREJUV Intense Pulsed Light System Family is a prescription home use device intended to provide phototherapeutic light to the body. It is specifically intended for:
The treatment of benign pigmented lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosecea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.

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

K142924

Submitter:	Shaser, Inc. 10 Maguire Road Lexington, MA 02421
Contact:	Anthony Burns Senior Director of Regulatory Affairs
Date Summary Prepared:	October 6, 2014
Device Trade Name:	Shaser Skin Beauty SkinREJUV™ Intense Pulsed Light System Family
Common Name:	Intense Pulsed Light Therapy System
Classification Name:	Powered Light Based Non-Laser Surgical Instrument with Thermal Effect 79-ONF, 21 CFR 878.4810
Equivalent Devices:	Sciton Profile Multi-Platform System (K070833) Shaser Skin Beauty Intense Pulsed Light System Family (K141583)
Device Description:	Shaser Skin Beauty SkinREJUV™ Intense Pulsed Light System Family devices are prescription home use, light-based skin care systems. The family includes an AC mains powered and battery powered version of the same device. The Principle of Operation is selective photothermolysis and the Mechanism of Action is to lighten or resolve lesions using light for preferentially heating. Emission activation is by finger switch. Device includes a limited life treatment head. Electrical requirement is 115 VAC, 15A, 50-60 Hz, single phase.
Intended Use:	Treatment of benign pigmented lesions and benign cutaneous vascular lesions.
Indications For Use:	The Shaser Skin Beauty SkinREJUV™ Intense Pulsed Light System Family is a prescription home use device intended to provide phototherapeutic light to the body. It is specifically intended for: The treatment of benign pigmented lesions including dyschromia, hyperpigmentation, melisma, ephelides (freckles); The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
Comparison:	The Shaser Skin Beauty SkinREJUV™ Intense Pulsed Light System Family has the identical 'Indications For Use', the identical 'Fundamental Science', and the same performance specifications as the (IPL platform of the) Sciton Profile Multi-Platform System.

	Family has the identical 'Fundamental Science', identical performance specifications, the same design, materials, and funtions as the Shaser Skin Beauty Intense Pulsed Light System Family.
Nonclinical Performance Data:	Bench testing for performance verification and electrical safety testing.
Clinical Performance Data:	Label comprehension and usability test of consumers' ability to understand the instructions for use and to evaluate their ability to use the device safely in a simulated home-use environment. • 150 study subjects were tested for label comprehension and 123 study subjects tested for usability. Both test populations included low literacy subjects. The results of the two tests confirm sufficient label comprehension and safe and appropriate use of the device.
Conclusion:	The results of the nonclinical and clinical performance data conclusively demonstrates that the proposed device is at least as safe and effective as the Sciton Profile Multi-Platform System and is a safe and effective device for the intended uses.
Additional Information:	None