Step Up Skin Laser, LLC
% Irving Wiesen
Official Correspondent
Law Offices of Irving L. Wiesen, P.C.
420 Lexington Avenue
Suite 2400
New York, New York 10170

November 14, 2018

Re: K182604
Trade/Device Name: New Era
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: September 20, 2018
Received: September 21, 2018

Dear Irving Wiesen:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Digitally signed by Neil R.P. Ogden
Date: 2018.11.14 16:24:31 -05'00'

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

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)*

K182604

Device Name
New Era Laser

Indications for Use *(Describe)*

The New Era Laser is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

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."

Tab #7 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number:

1. Date of Preparation

September 6, 2018

2. Sponsor

Step Up Skin Laser LLC
433 5th Ave, 6th floor ,
New York, NY 10016

Contact person: Michelle Hokama President
michellehokama911@gmail.com
cell number :347-642-2982
company: 646-577-3333 , 646-882-8479

Establishment Registration Number: Not yet registered

3. Submission Correspondent

Irving L. Wiesen, Esq.
Law Offices of Irving L. Wiesen, P.C.
420 Lexington Avenue - Suite 2400
New York, New York 10170
Tel. 212-381-8774
Fax 646-536-3185
Email: iwiesen@wiesenlaw.com
Website: www.wiesenlaw.com

4. Identification of Proposed Device

Trade Name: New Era

Common Name: Powered Laser Surgical Instrument

Regulatory Information:
Classification Name: Powered Laser Surgical Instrument

Classification: II; Product Code: GEX;
Regulation Number: 21 CFR 878.4810; Review Panel: General & Plastic Surgery

Intended Use:

The New Era is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

5. Device Description

The proposed device, New Era, is a surgical device, which is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI);

There is one model, FG 2000.

Table 1 Specifications

Model	FG 2000-D
Size	59*59*146 cm
Weight	45kg
Handpiece	Refer to Fig 16
Cooler Number	1

The main components of proposed device shown as following:
Table 2 Main Components of Proposed Device

Components	Function Description	Applied Model(s)
Handpiece	Deliver the laser to area to be treated	FG 2000

Touchscreen	The user interface and for controlling of the system	FG 2000
Emergency Switch	Stop the system in case of emergency situation	FG 2000
Key Switch	Start the system	FG 2000
Connector	Connection of the device with the handpiece	FG 2000
Indicator Lamp	Indicate current working state of the appliance	FG 2000
Foot Switch	Activate the laser emission	FG 2000

The proposed system provides 36 working modes, which are six modes for men and six modes for women, the men or women mode includes Parameter one, two, three, four, five and six mode respectively for different preset parameter combination, and each particular parameter preset mode includes three submode as mode 1, mode 2 and mode 3.

The difference for each mode is only the default parameter, but all parameters for each mode can be adjustable in the parameter range.

The treatment can be applied on different Fitzpatrick skin type, including I (White), II (White with pigment), III (Yellow), IV (Yellow with pigment), V (Brown) and VI (Black);

6. Identification of Predicate Device

Predicate K161692
Diode Laser Therapy Machine
Model FG2000D

Beijing ADSS Development Co., Ltd.

7. Non-Clinical Test Conclusion

The proposed device, New Era, Model FG2000, is identical in all respects to the predicate device.

It is made by the same manufacturer, utilizing the same controls, components, and processes of the predicate device.
Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
IEC 60601-2-2:2007, Medical Electrical Equipment - Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment;
IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification and requirements.
IEC 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.
ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity
ISO 10993-10:2002/Amd. 1: 2006, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity AMENDMENT 1
Performance Testing for Spot Size Accuracy and Energy Output Accuracy.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

	21 CF
nded for nent skin type skin. tion is n, stable nber of neasured after the eatment	The Diode I Removal Sy for hair ren permanent on all ski (Fitzpatrick VI), includi Permanent is defined as stable reduc number of when measu months afte of a trea

Table 3 General Comparison

Item	Proposed Device	Predicate Device
Product Code	GEX	GEX
Regulation Number	21 CFR 878.4810	21 CFR 878.4810
Intended Use	The New Era is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.	The Diode Laser Hair Removal System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.
Configuration	Main Unit	Main Unit

	Handpiece	Handpiece	SE
	Foot Control	Foot Control	SE
Principle of Operation	Diode Laser	Diode Laser	SE

Table 4 Performance Comparison

Item	**Proposed Device**	Predicate	**Remark**
Laser Type	Diode Laser	Diode Laser	SE
Laser Classification	Class IV	Class IV	SE
Laser Wavelength	808 nm	808 nm	SE
Spot Size	1.44 cm2	1.44 cm2	SE
Fluence	2-120J/ cm2	2-120J/ cm2	SE

Frequency	1-10Hz	1-10Hz	SE
Pulse Duration	9-143ms	9-143ms	SE
Power Supply	AC 110V/50Hz-60Hz	AC110V/50Hz-60Hz	SE
Dimension	59*59*146cm	59*59*146cm	SE
Weight	49g kg	49g	SE

Discussion

The proposed device, New Era, Model FG2000, is identical in all respects to the predicate device. It is made by the same manufacturer, utilizing the same controls, components, and processes of the predicate device.

Table 5 Safety Comparison

Item	**Proposed Device**	**Predicate Device**	**Remarks**
Patient Contact Materials and Biocompatibility			
Patient Contact Materials	Sapphire in handpiece and handpiece tip (Stainless Steel)	Sapphire in handpiece and handpiece tip (Stainless Steel)	SE
Cytotoxicity	No Cytotoxicity	No Cytotoxicity; no evidence of sensitization or irritation	SE
Sensitization	No evidence of sensitization		
Irritation	No evidence of irritation		
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	SE

EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	SE

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.