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5. 510(k) Summary

Speed 808 Diode Laser System
Beijing Toplaser Technology Co., Ltd.
(As required by 21 CFR 807.92)
K Number: K132989

1. Date Prepared: Dec. 20, 2013

2. Sponsor Information
Beijing Toplaser Technology Co., Ltd.
East 3rd Floor, Building M7, No.1 Jiuxianqiao East Road,
Chaoyang District, Beijing 100015, China
Contract Person: Zhang Xiaosong, General Manager
Phone: +86-10-64354759
Fax: +86-10-64356591

3. Proposed Device Information
Device Common or Usual Name: diode laser
Device Trade or Proprietary Name: Speed 808 Diode Laser System
Classification Name: Laser instrument, Surgical, Powered
Regulation Number: 21 CFR 878.481 0
Product Code: GEX
Panel: General and Plastic Surgery
Model: LD-1

4. Predicate Device
Modified Alma Lasers Family of Soprano XL™ Multi- Application Platforms [Soprano XL, Soprano XLi] (K102716)
Manufactured by Alma Lasers, INC.

5. Device Description
Speed 808 Diode Laser System are new devices for 510(k) submission and share the similar indication for use and safety compliance, similar design features and functional features with the predicate devices.
The complete system consists of a console, a handpiece connected to the

Add: East 3rd Floor, Building M7, NO.1 Jiuxianqiao East Road, Chaoyang District, Beijing 100015 China
Tel: +86-10-64354759 Web: www.toplaser.com Mail: office@toplaser.com.cn

system by an umbilical cord and a footswitch. There are two important components in the handpiece: a diode laser inserted in the handpiece and a sapphire-made aperture with an area of 10mmX10mm through which laser energy is emitted. A cooling system effectively works on the sapphire-made aperture and can ensure enough and continuous protection of skin. The handpiece is pressed against the patient's skin and a pulse of laser is delivered. To initiate energy output, the system requires the activation of the handpiece trigger or the footswitch. Laser specifications and other system features are controlled from the Operating Buttons and LCD screen on top of the console, which provide interface with the system computer.

6. Intended use/ Indications for Use

The new device Speed 808 Diode Laser System is intended for use in dermatologic and general surgical procedures.

The Speed 808 Diode Laser System is indicated for hair removal, permanent hair reduction.

The permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and I2 months after the completion of a treatment regimen.

The Speed 808 Diode Laser System is intended for use on all skin types (Fitzpatrick skin types I - VI), including tanned skin.

7. Substantial Equivalence

Speed 808 Diode Laser System shares the similar indications for use, design features, functional features, same safety compliance. Therefore Speed 808 Diode Laser System is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

8. Testing

Speed 808 Diode Laser System is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

- IEC 60825-1: Safety of Laser Products – Part 1: Equipment Classification and Requirements
- IEC 60601-2-22: Medical Electrical Equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
- IEC 60601-1: Medical Electrical Equipment – Part 1: General requirements for safety.
- IEC 60601-1-2: Medical Electrical Equipment -Part 1: General requirements for safety-2, Collateral Standard: Electromagnetic compatibility - Requirements and tests.
- UL 60601-1:2003 R6.03

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Tel: +86-10-64354759 . **Web**: www.toplaser.com **Mail**: office@toplaser.com.cn

Non-Clinical Conclusion:

Laboratory testing was conducted to validate and verify' that the proposed device, Speed 808 Diode Laser System met all design specifications and was substantially equivalent to the predicate device. No Clinical Information is required.

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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

Beijing Toplaser Technology Company, Ltd
Mr. Xiaosong Zhang
General Manager
East Third Floor, Building M7
#1 Jiuxiangquiao East Road
Chaoyang District, Beijing 100015
CHINA

January 23, 2014

Re: K132989
Trade/Device Name: Speed 808 diode laser 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: December 20, 2013
Received: December 26, 2013

Dear Mr. Zhang:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Joshua C. Nipper -S

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

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K132989
Device Name: Speed 808 Diode Laser System

Indications For Use:
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Prescription Use YES AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of __1___

Neil R Ogden -S
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(Division Sign-Off) for BSA

Division of Surgical Devices

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