APR 18 2014

5. 510(k) Summary

CO2-2B Galaxy CO2 Laser System
Beijing Toplaser Technology Co., Ltd.
(As required by 21 CFR 807.92)
K Number: K133915

1. Date Prepared: November 29, 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: +86-10-64344735
Fax: +86-10-64356591

3. Proposed Device Information:
Device Common or Usual Name: CO2 Laser
Device Trade or Proprietary Name: CO2-2B Galaxy CO2 Laser System
Classification Name: Powered Laser Surgical Instrument
Regulation Number: 21 CFR 878.4810
Product Code: ONG, GEX
Panel: General and Plastic Surgery
Model: CO_2-2B

4. Predicate Devices:
eCO2 Laser System（K091115），Manufactured by Lutronic Corporation.
YouLaserCO2 Laser System (K111592) , Manufactured by Quanta System SpA
Slim Evolution II CO2 Laser and Delivery Device Accessories (K110984) Manufactured by Lasering S.r.l .

5. Device Description
Galaxy CO2 Laser System consists of Mainframe, Optical Delivery System, Protective Glasses and Footswitch. Mainframe consists of CO2 laser generator, laser power supply, control device, safety protection system and cooling system. Optical delivery

system consists of articulated arm, aiming beam, normal handpiece and fractional scanner handpiece.
Galaxy CO2 Laser System produces a beam of coherent infrared light ---10.6μm laser which is near the peak of tissue water absorption. When the water in the tissue absorbs the laser energy, it heats up. The heating causes instantaneous vaporization of the target issue. Equipped with the scanner, the system delivers a high-speed laser scan with micro spots for optional control of treatment area and depth.

6. Intended Use / Indications for Use

Galaxy CO2 Laser System is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery, general surgery.
Dermatology, Plastic Surgery and General Surgery procedures:

Laser skin resurfacing
Treatment of furrows and wrinkles
Removal of skin tags, actinic keratosis, acne scars, keloids, tattoos, telangiectasia, squamous and basal cell carcinoma, warts and uneven pigmentation.
Treatment of cysts, abscesses, hemorrhoids and other soft tissue applications.
Blepharoplasty
Site preparation for hair transplants

The fractional scanner is for treatment of wrinkles and skin resurfacing.

7. Substantial Equivalence

The Galaxy CO2 Laser System (CO2-2B) shares the same technology, the same indications for use and safety compliance, similar design features, functional features, and therefore are substantially equivalent to the predicate devices, eCO2 laser system (K091115), YouLaser CO2 Laser System（K111592）, Slim Evolution II CO2 Laser and Delivery Device Accessories（K110984）.

8. Testing

Galaxy CO2 Laser System (CO2-2B) is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

· IEC 60601-1: Medical Electrical Equipment – Part 1: General requirements for safety.
· IEC 60601-2-22: Medical Electrical Equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.
·IEC 60825-1: Safety of laser products - Part 1: Equipment classification, and requirements
·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

Non-Clinical Conclusion:
Laboratory testing was conducted to validate and verify' that the proposed device, Galaxy CO2 Laser System (CO2-2B) met all design specifications .and was substantially equivalent to the predicate devices. No Clinical Information is required.

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

April 18, 2014

Beijing Toplaser Technology Company, Ltd.
Mr. Zhang Xiaosong
General Manager
East 3rd Floor Building M7, No. 1 Jiuxianqiao East Road
Chaoyang District, Beijing, 100015
CHINA

Re: K133915
Trade/Device Name: CO2-2B Galaxy CO2 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: ONG, GEX
Dated: January 16, 2014
Received: January 22, 2014

Dear Mr. Xiaosong:

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,

David Krause -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

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)*
K133915

Device Name
CO2-2B Galaxy CO2 Laser System

Indications for Use *(Describe)*

The CO2-2B Galaxy CO2 Laser System is intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery, general surgery.

Dermatology, Plastic Surgery and General Surgery procedures:

Laser skin resurfacing.
Treatment of furrows and wrinkles.
Removal of skin tags, actinic keratosis, acne scars, keloids, tattoos,telangiectasia, squamous and basal cell carcinoma, warts and uneven pigmentation.
Treatment of cysts, abscesses, hemorrhoids and other soft tissue applications.
Blepharoplasty.
Site preparation for hair transplants.
The fractional scanner is for treatment of wrinkles and skin resurfacing.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.04.18 09:58:37 -04'00'

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