K131837

HONKON
北京宏强富瑞技术有限公司

510(k) Premarket Notification Submission

JAN 2 2 2014

**510(k) Summary**

In accordance with 21 CFR 807.92 the following summary of information is provided:

| | |
|---|---|
| Date: | 18 June, 2013 |
| Submitter: | Beijing Honkon Technologies Co., Ltd.<br>Address: No.3 Building, No.11 Yard, Kangding Street, BDA, 100176, Beijing, P.R.China |
| Primary Contact Person: | Mike Gu<br>Address: 7th floor, Jingui Business Building, 982 Congyun Road, Baiyun District, 510420, Guangzhou, China<br>OSMUNDA Medical Device Consulting Co., Ltd.<br>Tel: (+86) 20 6232 1333<br>Fax:(+86) 208633 0253 |
| Secondary Contact Person: | Zhao Li<br>Management representative<br>Beijing Honkon Technologies Co., Ltd.<br>Tel: (+86) 10-56370050<br>Fax: (+86) 10-56370076-610 |
| Device: Trade Name: | $CO_2$ Laser (10600nm) |
| Common/Usual Name: | $CO_2$ Laser |
| Regulatory Number: | 878.4810 |
| Regulation Name: | Laser surgical instrument for use in general and plastic surgery and in dermatology |
| Product Code: | GEX |
| Predicate Device(s): | K080496 |
| Device Description: | The CO2 Laser consists of semiconductor solid-state lasers, switching power supply, laser power, treatment handle, key switch, cooling system and accessories. The CO2 Laser produces a beam of coherent infrared light with 10600nm wavelength.<br><br>The CO2 laser comprises five models: YILIYA-10600AH, YILIYA-10600AL, YILIYA-10600CH, Aeslight-10600EH, Aeslight-Ultra peel; their technical parameters and functions are the same, the only difference is their appearances and sizes. |
| Intended Use: | The $CO_2$ Laser (10600nm) is indicated for use in dermatological procedures requiring ablation, resurfacing and coagulation of soft tissue. |

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Technology: The $CO_2$ laser therapy device emits a highly focused laser beam. Absorbed by water of the soft tissue, the CO2 laser incorporating the advanced technologies can immediate ablate discrete columns of tissue without charring. This device can be used in multiple specialties, such as Oral Surgery, Plastic Surgery, Dermatology.

Determination of Substantial Equivalence:

| **Specification** | **Predicate Device K080496** | **Proposed CO2 Laser** |
|---|---|---|
| *Manufacturer* | Lutronic Corporation | Honkon |
| *Intended Use* | It is indicated for use in dermatological procedures requiring ablation (removal), resurfacing and coagulation of soft tissue. | The $CO_2$ Laser is indicated for use in dermatological procedures requiring ablation (removal), resurfacing and coagulation of soft tissue. |
| *Energy output* | 2-240mj | 2-200mj |
| *Laser transfer method* | Articulated Arm with Handpiece | Articulated Arm with Handpiece |
| *$CO_2$ RF Module Maximum Power* | Maximum 30w at continuous wave | Maximum 30w at continuous wave |
| *Wavelength (nm)* | 10600 | 10600 |
| *Pulse duration (ms)* | 5-100 | 5-100 |
| *Frequency (Hz)* | 10-200Hz | 10-200Hz |
| *Patient contacting materials* | Aluminum | Aluminum |
| *Compatibility with environment and other devices* | Comply with the IEC 60601-1-2 | Comply with the IEC 60601-1-2 |
| *Electrical Safety* | Comply with the IEC 60601-1 | Comply with the IEC 60601-1 |
| *Radiation Safety* | IEC 60825-1;<br>IEC 60601-2-22 | IEC 60825-1;<br>IEC 60601-2-22 |
| *Biocompatibility* | ISO 10993-5;<br>ISO 10993-10 | ISO 10993-5;<br>ISO 10993-10 |

| | | |
|---|---|---|
| *Other: Device Specific Guidance Requirements for Comparison* | Guidance on the Content and Organization of a Premarket Notification for a Medical Laser;<br>21 CFR 1040.10 | Guidance on the Content and Organization of a Premarket Notification for a Medical Laser;<br>21 CFR 1040.10 |

Conclusion: The $CO_2$ Laser and its application comply with standards as detailed in section 9, 11 and 17 of this premarket notification. Therefore, Beijing Honkon states that the non-clinical tests determined that the $CO_2$ Laser to be as safe, as effective and performance is substantially equivalent to the predicate device(s).

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

Osmunda Medical Device Consulting Co., Ltd.
Mike Gu
Regulatory Affairs Manager
7th floor, Jingui Business Building, 982 Congyun Road,
Baiyun District, 510420, Guangzhou, China

January 22, 2014

Re: K131837
Trade/Device Name: CO2 Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 15, 2014
Received: January 17, 2014

Dear Mr. Gu:

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

Dr. Binita Ashar
Acting Director
For Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Premarket Notification Submission

510(k) Number: K131837

Device Name: CO2 Laser (10600nm)

Indications for Use:

The CO2 Laser (10600nm) is indicated for use in dermatology procedures requiring ablation, resurfacing and coagulation of soft tissue.

Prescription Use X AND/OR Over-The-Counter Use_
(Part 21 CFR 801 Subpart D) (Part 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)

Neil R Ogden -S
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(Division Sign-Off) for BSA
Division of Surgical Devices
510(k) Number K131837