K131838



APR 2 4 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.
Address: No.3 Building, No.11 Yard, Kangding Street, BDA, 100176, Beijing, P.R.China

Primary Contact Person: Mike Gu
Regulatory Affairs Manager
OSMUNDA Medical Device Consulting Co., Ltd.
Tel: (+86) 20 6232 1333
Fax: (+86) 208633 0253

Secondary Contact Person: Li Zhao
Management Representative
Beijing Honkon Technologies Co., Ltd.
Tel: (+86) 10-56370050
Fax: (+86) 10-56370076-610

Trade Name: Diode Laser for Hair Removal

Common/Usual Name: Diode Laser

Classification Names: Powered Laser Surgical Instrument

Regulation number 878.4810

Product Code: GEX

Predicate Device(s): K112031

Device Description: The diode laser for hair removal is generally included components such as semiconductor solid-state lasers, switching power supply, laser power, treatment handle, key switch, cooling system and accessories. Its models are 808CL, 808CM, 808CH, 808EH, 808BL, 808BM, 808BH, 808FH, 808HGG and 808DH.Theirs differences are between the size of device which is described in the table below:

| Model | Dimension (width* length* high) mm | |
|---|---|---|
| | Before package | After package |
| 808CL | 815*530*1420 | 895*590*1510 |
| 808CM | 790*540*1300 | 870*600*2200 |
| 808CH | 775*510*1395- | 855*570*1485 |
| 808EH | 810*530*1060 | 890*570*1960 |
| 808BL | 810*550*1300 | 890*610*1390 |
| 808BM | 820*590*1210 | 900*650*1300 |
| 808BH | 820*590*1280 | 900*650*1370 |
| 808DH | 780*620*1110 | 860*680*1200 |

| | | |
|---|---|---|
| 808FH | 785*620*1180 | 865*680*1270 |
| 808HGG | 780*630*1290 | 860*690*1380 |

Intended Use:

The Honkon's diode laser for hair removal is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI).

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

Technology:

The principle of laser hair removal is selective photothermolysis, the matching of a specific wavelength of light and pulse duration to obtain optimal effect on a targeted tissue with minimal effect on surrounding tissue. Laser can cause localized damage by selectively heating melanin and follicle while not heating the rest of the skin.

Determination of Substantial Equivalence:

| **Specification** | **Predicate Device** | **Proposed device** |
|---|---|---|
| *K number* | K112031 | - |
| *Manufacturer* | Alma Lasers, Inc. | Beijing Honkon Technologies Co., Ltd |
| *Model* | Alma Lasers Modified Diode Laser Module with HR Treatment Mode for | 808CL, 808CM, 808CH, 808EH, 808BL, 808BM, 808BH, 808FH, 808HGG |

| | | |
|---|---|---|
| *Intended Use* | The HR Mode is intended for hair removal, permanent hair reduction. (Fitzpatrick skin types I-VI), including tanned skin. | The diode laser for hair removal is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI).<br>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 |
| *Wavelength (nm)* | 810 | 808 |
| *Output power (W)* | 30 | 30 |
| *Fluence (Energy Density)* | <120 J/cm$^2$ | <120 J/cm$^2$ |
| *Pulse Duration* | 5-200ms | 5-300 ms |
| *Frequency* | Up to 10Hz | 1-10Hz |
| *Spot Size* | 12cm$^2$ | 12mm$^2$ |
| *Material* | Sapphire | Sapphire |
| *Cooling* | Contact cooling | Contact cooling |
| *Anatomical Sites* | Axilla, Facial, Neck | Axilla, Facial, Neck |
| *Electrical Safety* | Comply with IEC 60601-1 and IEC 60601-1-2 | Comply with IEC 60601-1 and IEC 60601-1-2 |
| *Radiation Safety* | Comply with IEC 60601-2-22, IEC 60825-1 and 21 CFR 1040 PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS | Comply with IEC 60601-2-22, IEC 60825-1 and 21 CFR 1040 PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS |

Conclusion: The Diode Laser for Hair Removaland its application comply with standards as detailed in section 9, 11 and 17 of this premarket notification. Therefore, Beijing Honkonstatesthat the non-clinical tests determined that the Diode Laser for Hair Removal 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

April 24, 2014

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

Re: K131838
Trade/Device Name: Diode Laser for Hair Removal
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: March 25, 2014
Received: March 27, 2015

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,

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 on last page.*

510(k) Number *(if known)*
K131838

Device Name
Diode Laser for Hair Removal

Indications for Use *(Describe)*

The diode laser for hair removal is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI).

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)

**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
2014.04.23 15:34:14 -04'00'



For BSA

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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