JAN 16 2014

Exhibit #4 510(k) Summary

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

The assigned 510(k) Number: __K131857_

1. Date of Prepared: 01/11/2014

2. Sponsor

Beijing Honkon Technologies Co., Ltd.
No.3 Building, No.11 Yard, Kangding Street, BDA, 100176,Beijing, P.R.China

Establishment Registration Number: Not yet registered

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Position: Management Representative
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3. Submission Correspondent

Diana Hong & Tarzan.Wang
Mid-Link Consulting Co., Ltd
P.O. Box 237-023, Shanghai, 200237, China
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4. Proposed Device Identification

Proposed Device Name: Q-Switched ND:YAG Laser
Device Common Name: Laser Device
Proposed Device Model: YILIYA- 1064QCH, YILIYA- 1064QCL, Aeslight- 1064QEH

Classification:
Classification Name: powered laser surgical instrument
Classification: II;
Product Code: GEX;
Regulation Number: 21 CFR 878.4810;
Review Panel: General & Plastic Surgery;

Intended Use Statement:

1064 nm wavelength:

Tattoo Removal (Dark Ink, Black & Blue)

Ota's nevus

532 nm wavelength:

Tattoo Removal (Light Ink, Red, Sky Blue and Green)

Treatment of Pigmented Lesions

Solar Lentiginos

Senile Lentiginos

5. Predicate Device Identification

510(k) Number: K063834
Product Name: RevLite™ Q-Switched Nd:YAG Laser System
Manufacturer: Hoya ConBio, Inc.

6. Device Description

The proposed device includes three models as YILIYA- 1064QCH, YILIYA- 1064QCL and Aeslight-1064QEH, the differences between three models described in the subsection 5 specification.
The proposed device is the laser system with modularization and multi-wavelength, includes the

waveform as 1064 nm and 532 nm.

The proposed device consisted by control system, power supplier, cooling system, laser generator, articulated arm and foot switch.

7. Non-Clinical Test Conclusion

Bench 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:

a) IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
b) IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

c) IEC 60601-2-22 (1995) - Medical Electrical Equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic.
d) IEC 60825-:2007 Safety of laser products - Part 1: Equipment classification and requirements

8. Technological Characteristics Comparison

The proposed device has the same technological characteristics with the predicate device, such as Laser Medium, wavelength, control method and intended use.

9. Substantially Equivalent Conclusion

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

Table III-1 Comparison Table

ITEM	Proposed Device			Predicate Device k063834
Product Name	YILIYA-1064QCH	YILIYA-1064QCL	Aeslight-1064QEH	RevLite™ Q-Switched Nd:YAG Laser System
Laser Medium	Nd:YAG			Nd:YAG
wavelength	1064 nm 532 nm			1064 nm 532 nm
Output energy	800 mJ at max.			1600 mJ @ 1064 nm 500 mJ @ 532 nm
Max. Energy Density	25.47J/cm^2 at max.			22.64J/cm^2
Spot Size	2-7 mm			3, 4, 6&8 mm @ 1064 nm 2, 3, 4&6 mm @532 nm
Pulse Width	6-10 ns			5-20 ns

Repetition Rate	1-10 Hz	1, 2, 5, 10 Hz
Power calibration	The device is calibrated by laser energy/power meter no less than 1 time each year	---
Laser Class	Class 4	Class 4
Aiming Beam	A focusing device (viewfinder) fitted on the end instead of aiming beam And A red aiming beam for 1064 QEH	Red Aiming Beam

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 Honkon Technologies Company, Ltd.
% Ms. Diana Hong
Mid-Link Consulting Company, Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

January 16, 2014

Re: K131857
Trade/Device Name: YILIYA-1064QCH, YILIYA-1064QCL, and Aeslight-1064QEH
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 2, 2013
Received: December 6, 2013

Dear Ms. Hong:

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

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)*
K131857

Device Name
YILIYA- 1064QCH, YILIYA- 1064QCL, Aeslight- 1064QEH

Indications for Use *(Describe)*
1064 nm wavelength:
Tattoo Removal (Dark Ink, Black & Blue)
Ota's nevus

532 nm wavelength:
Tattoo Removal (Light Ink, Red, Sky Blue and Green)
Treatment of Pigmented Lesions
Solar Lentiginos
Senile Lentiginos

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
2014.01.14 16:15:36 -05'00'