K083899 Page 10 of 10

HOYA ConBio
47733 Fremont Boulevard, Fremont, California 94538
510-445-4500 www.conbio.com 510-445-4550 Fax

JUN - 1 2009

Submitter:	HOYA ConBio, Inc. 47733 Fremont Blvd. Fremont, California 94538 Phone: 510-445-4500 Fax: 510-445-4550
Contact:	Mr. Jim Green Vice President of Engineering
Date Summary Prepared:	April 3, 2009
Device Trade Name:	RevLite™ Q-Switched Nd:YAG Laser Systems
Common Name:	Dermatology Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX
Classification Code:	878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide. (2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.
Equivalent Device(s):	Alma, Harmony XL Multi-Platform (Q-Switched Nd:YAG hand piece) (K072564) Candela VBeam, VBeam Laser (K033461, K021180) and Sclerolaser (K013748) Cynosure, Photogenica/VLS- Star Laser (K053608) Iridex, Diolite2- 532 (K964074)
Device Description:	The entire laser unit and controls are contained in a single console. Electrical power is supplied to the console by the facility's power source. Laser energy produced within the device is delivered to the tissue by means of an articulated arm and a specially designed MultiSpot Handpiece (532 nm and 1064 nm) or optional Multilite Dye Laser Handpiece (650 nm and 585 nm). The user activates laser emission by means of a footswitch.

K083899 Page (2) of (2)

	The RevLite Systems are designed to provide laser energy for use in a variety of dermatological procedures (see indications for use). The 532 nm and 1064 nm wavelengths and optional 650 nm and 585 nm wavelengths are absorbed by pigment and other chromophores within the skin to create the desired clinical effect. The laser incorporates very narrow laser pulses (5-20 ns) designed to apply higher peak power over a very short period to minimize the time to absorb heat into the tissue. .
Intended Use:	General: Incision, Excision, Ablation and Vaporization of Soft Tissue for General Dermatology, Dermatologic and General Surgical Procedures for Coagulation and Hemostasis Specific: For use for the following indications: Treatment of Epidermal Pigmented Lesions, Treatment of Dermal Pigmented Lesions, Nevus of Ota, Laser skin resurfacing procedures for the treatment of acne scars and wrinkles, Tattoo Removal: Dark Ink: (Black & Blue) Light Ink: (Red, Sky Blue, Green), Treatment of Vascular Lesions, Removal or lightening of unwanted hair with or without adjuvant preparation. *Benign cutaneous lesions, such as, but not limited to: striae and scars. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength).*
Comparison:	The RevLite™ Laser Systems are comparable to their predicate devices in terms of their indications for use, technical specifications, operating performance features, and general design features.
Nonclinical Performance Data:	None
Clinical Performance Data:	None.
Additional Information:	None requested at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

HOYA ConBio, Incorporated
% Ms. Lisa Burns
Liza Burns and Associates
19722 Westview Drive
Twain Harte, California 95383

JUN - 1 2009

Re: K083899
Trade/Device Name: RevLite™Q-Switched Nd:YAG 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: II
Product Code: GEX
Dated: May 15, 2009
Received: May 18, 2009

Dear Ms. Burns:

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083899 Page 3 of (2)

Device Name: RevLite™ Q-Switched Nd:YAG Laser System

Intended Use: Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology, Dermatologic and General Surgical Procedures for Coagulation and Hemostasis.

Specific Indications:.

1064 nm wavelength

- Tattoo Removal (dark ink: blue and black)
- Nevus of Ota
- Removal or lightening of hair with or without adjuvant preparation.
- Skin Resurfacing for Acne Scars and Wrinkles
- *Benign cutaneous lesions, such as, but not limited to: striae and scars (excludes the 650nm wavelength)*
- *Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)*

532 nm wavelength *(nominal delivered energy of 585 nm and 650 nm with the Optional Multilite Dye Laser Handpiece)*

- Tattoo removal (light ink: red, sky blue, green)
- Vascular lesions including but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi
- Epidermal Pigmented lesions including but not limited to: cafe-au-lait birthmarks, solar lentiginos, senile lentiginos, Becker's nevi, Freckles, Nevus spilus
- Skin Resurfacing for Acne Scars and Wrinkles
- *Benign cutaneous lesions, such as, but not limited to: striae and scars (excludes the 650nm wavelength)*
- *Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)*

Neil R. Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083899

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083899