K103118

5. Special 510(k) Summary

Handpiece Adaptor Accessory for the RevLite Q-Switched Nd:YAG Laser System: Special 510k Summary

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NOV 19 2010

Submitter:	HOYA Photonics, Inc. (dba HOYA ConBio, Inc.) 47733 Fremont Blvd. Fremont, California 94538 Phone: 510-445-4500 Fax: 510-445-4550
Contact:	Donna K. Templeman Regulatory Consultant for HOYA ConBio, Inc.
Date Summary Prepared:	October 15, 2010
Device Trade Name:	RevLite Q-Switched Nd:YAG Laser System
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:	RevLite Q-Switched Nd:YAG Laser System (K083899)

Device Description:	The RevLite Q-Switched Nd:YAG Laser System with Handpiece Adaptor consists of a electrically powered Console in which laser energy produced within the system is delivered to the tissue by means of an articulated arm, Handpiece Adaptor and specially designed Handpieces. The user activates laser emission by means of a footswitch.
Intended Use:	Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology, Dermatologic and General Surgical Procedures for Coagulation and Hemostasis.
Comparison:	The RevLite Q-Switched Nd:YAG Laser System with Handpiece Adapator is comparable to its parent predicate device (RevLite Q-Switched Nd:YAG Laser System with LCD) in terms of its intended use, 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hoya Photonics, Inc.
% DKT Consulting
Ms. Donna K. Templeman
1105 Sunset Creek Lane
Pleasanton, California 94566

NOV 19 2010

Re: K103118
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: Class II
Product Code: GEX
Dated: October 15, 2010
Received: October 21, 2010

Dear Ms. Templeman:

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.

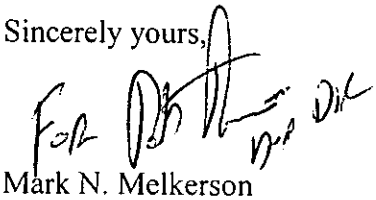
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



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

Enclosure

4. Indications for Use Statement

NOV 19 2010

Indications for Use
510(k) Number (if known): K 103118

Device Name: Handpiece Adaptor (HPA) 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)
- Dermal Pigmented Lesions
- 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)

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)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices
Office of Device Evaluation (ODE)

510(k) Number K103118