K133254

MAR - 5 2014

**510(k) Summary for RevLite Q-Switched Nd: YAG Laser System**

**A. Sponsor**

Cynosure, Inc.
5 Carlisle Road
Westford, MA 01886

**B. Contact**

Huda Yusuf, MSc.
Senior Regulatory Affairs Specialist
781-993-2311
hyusuf@cynosure.com
or
Connie Hoy
Vice President of Regulatory Affairs
781-993-2414
choy@cynosure.com

**C. Device Name**

| | |
|---|---|
| Trade Name: | RevLite Q-Switched Nd: YAG Laser System |
| Common/usual Name: | Medical Laser System |
| Classification Name: | GEX-Powered laser surgical instrument, General & Plastic Surgery<br>21 CFR 878.4810, Class II |

**D. Predicate Device**

| | |
|---|---|
| Trade Name: | RevLite Q-Switched Nd:YAG Laser System |
| Common/usual Name: | Dermatology Laser System |
| Classification Name: | GEX-Powered laser surgical instrument, General & Plastic Surgery<br>21 CFR 878.4810, Class II |
| Premarket Notification: | HOYA PHOTONICS, Inc., K103118 (11/19/2010) |
| | |
| Trade Name: | SPECTRA Q-Switched Nd:YAG |
| Common/usual Name: | Laser System with Dye Handpieces |
| Classification Name: | GEX-Powered laser surgical instrument, General & Plastic Surgery<br>21 CFR 878.4810, Class II |
| Premarket Notification: | Lutronic Corporation, K113588 (2/2/2012) |
| | |
| Trade Name: | Palomar Q-YAG 5™ Nd:YAG Laser System |
| Common/usual Name: | Q: Switched Nd:YAG |
| Classification Name: | GEX-Powered laser surgical instrument, General & Plastic Surgery<br>21 CFR 878.4810, Class II |
| Premarket Notification: | Palomar Medical Technologies, Inc., K061436 (12/06/2006) |

**E. Device Description**

The RevLite Q-Switched Nd:YAG Laser System consist of an electrically powered Console, in which laser energy produced within the system is delivered to the tissues by means of an articulated arm, Handpiece Adaptor and specially designed handpieces. The user activates laser emission by means of a footswitch.

**F. 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; including, but not limited to: Nevus of Ota, Lentigines, Nevi, Melasma and Cafe-au-lait
- Removal or lightening of hair with or without adjuvant preparation.
- Skin Resurfacing for Acne Scars and Wrinkles
- Benign cutaneous lesions; including, 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, seborrheic keratosis
- Skin Resurfacing for Acne Scars and Wrinkles
- Benign cutaneous lesions; including, 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)

The RevLite Q-Switched Nd:YAG Laser System (K103118) is currently indicated for the treatment of Dermal Pigmented lesions (1064 nm wavelength) and Epidermal Pigmentation lesions (532 nm wavelength). Both dermal and epidermal pigmented lesions are types of benign pigmented lesions. Cynosure is seeking to clarify the indications for use statement for RevLite Q Switched laser to include examples of other pigmented lesions. There have been no changes to the device and the submission is only related to clarification of pigmented lesions.

**G. Technological Characteristics**

The laser systems have the same technological characteristics. All of the devices are Q-switched Nd:YAG lasers operating at wavelengths of 1064 nm and 532 nm. Additionally, dye handpieces are available that convert the 532 nm wavelength beam into 585 nm or 650 nm wavelengths. The RevLite Q Switched Laser System has the exact same technological characteristics as the previously cleared RevLite Q Switched Laser System (K103118). The clarified RevLite Indications for Use statement has the same example of benign cutaneous lesions, vascular lesions and epidermal pigmented treated as the RevLite, Spectra and Palomar predicates.

| | **Proposed Device** | **Predicate Device** | **Predicate Device** | **Predicate Device** |
|---|---|---|---|---|
| 510(k)# | | K103118 | K113588 | K061436 |
| Manufacturer | Cynosure (HOYA ConBio) | Cynosure (HOYA ConBio) | Lutronic Corporation | Palomar Medical Technologies, Inc. |
| Device Name | RevLite Q-Switched Nd:YAG Laser System | RevLite Q-Switched Nd:YAG Laser System | Spectra Q-Switched Nd:YAG Laser system | Q-YAG 5 Nd:YAG laser system |
| Clearance Date | | 11/19/2010 | 2/22/2012 | 12/6/2006 |
| Classification/ Regulation | 21 CFR 878.4810 (GEX) | 21 CFR 878.4810 (GEX) | 21 CFR 878.4810 (GEX) | 21 CFR 878.4810 (GEX) |
| Laser Medium | Nd:YAG | Nd:YAG | Nd:YAG | Nd:YAG |
| Operating Parameters | Q-Switched | Q-Switched | Q-Switched | Q-Switched |
| Wavelength | 1064nm / 532 nm | 1064nm / 532 nm | 1064nm / 532 nm | 1064nm / 532 nm |
| ***Pulse Characteristics:*** | | | | |
| Maximum Pulse Duration | 7 - 20 ns | 7 - 20 ns | 5 - 10 ns | 3 ns |
| Energy Delivered | 1.6 J | 1.6 J | 1.2 J | 0.4 J |
| Fluence | 1 - 8 J/cm$^2$ @ 3 – 8 mm spot size | 1 - 8 J/cm$^2$ @ 3 – 8 mm spot size | 5 - 10 J/cm$^2$ | 3.45 J/cm$^2$ @ 4 mm spot size |
| Spot Sizes | 2-8.5mm range with 0.1mm increments | 2-8.5mm range with 0.1mm increments | 3,4,5,6,7,8 mm / 1,2,3,4,5,6,7 mm (option) | 2 mm, 4 mm, 6 mm (optional) |
| Repetition Rate | Single shot, 1,2,5, 10 Hz | Single shot, 1,2,5, 10 Hz | Max. 10 Hz | 1-10 Hz |
| ***Physical Characteristics:*** | | | | |
| System Dimensions | 31.8" (H) x 12" (W) x 28.5" (D) | 31.8" (H) x 12" (W) x 28.5" (D) | 11.6" (W) x 25.8" (L) x 66.93" (H) | 18" (L) x 19" (H) x 17" (D) |
| System Weight | 131 lbs. | 131 lbs. | 194 lbs. | 88 lbs. |
| Electrical Requirements | AC 230 V, 50/60 Hz | AC 230 V, 50/60 Hz | AC 220-230V, 50/60 Hz | 100 - 240 V, 50/60 Hz |
| Maximum Power | 20W | 20W | 240MW | 4W |

***Indications for Use Statement***

| | Proposed Device | Predicate Device | Predicate Device | Predicate Device |
|---|---|---|---|---|
| Intended Use / Indications for Use | 1064 nm wavelength<br>Tattoo Removal (dark ink: blue and black)<br>Dermal Pigmented Lesions; including, but not limited to: Nevus of Ota, Lentigines, Nevi, Melasma and Cafe-au-lait<br>Removal or lightening of hair with or without adjuvant preparation.<br>Skin Resurfacing for Acne Scars and Wrinkles<br>Benign cutaneous lesions; including, but not limited to: striae and scars (excludes the 650nm wavelength)<br>Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)<br><br>532 nm wavelength (nominal delivered energy of 585 nm and 650 nm with the Optional Multilite Dye Laser Handpiece)<br>Tattoo removal (light ink: red, sky blue, green)<br>Vascular lesions including but not limited to: port wine | 1064 nm wavelength<br>Tattoo Removal (dark ink: blue and black)<br>Dermal Pigmented Lesions<br>Nevus of Ota<br>Removal or lightening of hair with or without adjuvant preparation.<br>Skin Resurfacing for Acne Scars and Wrinkles<br>Benign cutaneous lesions, such as, but not limited to: striae and scars<br>excludes the 650nm wavelength)<br>Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)<br><br>532 nm wavelength (nominal delivered energy of 585 nm and 650 nm with the Optional Multilite Dye Laser Handpiece)<br>Tattoo removal (light ink: red, sky blue, green)<br>Vascular lesions including but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry | 1064 nm Wavelength<br>Tattoo removal: dark ink (black, blue and brown)<br>Removal of Nevus of Ota<br>Removal or lightening of unwanted hair with or without adjuvant preparation.<br>Treatment of Common Nevi<br>Skin resurfacing procedures for the treatment of acne scars and wrinkle<br>Treatment of melasma<br><br>532nm Wavelength (nominal delivered energy of 585 rim and 650 rim with optional dye handpieces):<br>Tattoo removal: light ink (red, tan, purple, orange, sky blue, green)<br>Removal of Epidermal Pigmented Lesions<br>Removal of Minor Vascular Lesions including but not limited to telangiectasias<br>Treatment of Lentigines<br>Treatment of Cafe-Au-lait<br>Treatment of Seborrheic Keratoses<br>Treatment of Post Inflammatory Hyper Pigmentation<br>Treatment of Becker' s Nevi, | 1064 nm Wavelength<br>Indicated for skin resurfacing with or without adjuvant preparation, dark ink tattoo removal (e.g., black ink), removal of pigmented lesions, including, but not limited to, lentigines, nevi, melasma, and cafe-au-lait, and the removal or lightening of hair.<br><br>532 nm Wavelength<br>Indicated for the removal of red ink tattoos, treatment of vascular lesions, including facial and leg veins, telangiectasias, angiomas, hemangiomas, portwine stains, and most pigmented lesions (e.g., lentigines, ephelides). The 1064/532 nm blended wavelength is indicated for tattoo removal. |

*Indications for Use Statement*

| | Proposed Device | Predicate Device | Predicate Device | Predicate Device |
|---|---|---|---|---|
| | birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi<br>Epidermal Pigmented lesions; including, but not limited to: cafe-au-lait birthmarks, solar lentiginos, senile lentiginos, Becker's nevi, Freckles, Nevus spilus, seborrheic keratosis<br>Skin Resurfacing for Acne Scars and Wrinkles<br>Benign cutaneous lesions; including, but not limited to: striae and scars (excludes the 650nm wavelength)<br>Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength) | angioma, spider nevi<br>Epidermal Pigmented lesions including but not limited to: cafe-au-lait birthmarks, solar lentiginos, senile lentiginos, Becker's nevi, Freckles, Nevus spilus<br>Skin Resurfacing for Acne Scars and Wrinkles<br>Benign cutaneous lesions, such as, but not limited to: striae and scars (excludes the 650nm wavelength)<br>Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength) | Freckles and Nevi Spilus | |

**H. Substantial Equivalence**

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s", the proposed device, RevLite Q-Switched Nd:YAG Laser System is substantially equivalent to the predicate device in terms of intended use, technological characteristics, and performance characteristics. The RevLite Q-Switched Nd:YAG Laser System is as safe, as effective, and performs as well as the predicate devices.

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

March 5, 2014

Cynosure Incorporated
Mrs. Huda Yusuf, MSc.
Senior Regulatory Affairs Specialist
5 Carlisle Road
Westford, Massachusetts 01888

Re: K133254
Trade/Device Name: RevLife 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: December 4, 2013
Received: December 5, 2013

Dear Mrs. Yusuf:

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,

Felipe Aguel

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

**Indications for Use Statement**

**510(k) number** K133254

**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)
- Dermal Pigmented Lesions; including, but not limited to: Nevus of Ota, Lentigines, Nevi, Melasma and Cafe-au-lait
- Removal or lightening of hair with or without adjuvant preparation.
- Skin Resurfacing for Acne Scars and Wrinkles
- Benign cutaneous lesions; including, 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, seborrheic keratosis
- Skin Resurfacing for Acne Scars and Wrinkles
- Benign cutaneous lesions; including, 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 ___√___ (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)

Felipe Aguel Date: 2014.03.05 11:44:57 -05'00'

(Division Sign-Off) for BSA
Division of Surgical Devices
510(k) Number K133254