

Section 4
510(k) Summary Statement
Hyperion Long Pulsed Nd:YAG Laser

K132286
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JAN 22 2014

Section 4 - This 510(k) Summary of safety and effectiveness is submitted in accordance with the requirements of 21 CFR §807.92

Submitter's Information

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Submitter: Scarlet RF, Inc.

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Preparation Date: 04/22/2013

Device Trade Name: Hyperion

Common Name: Long Pulsed Nd:YAG Dermatological Laser

Classification Name: Instruments, Surgical, Powered, Laser 79-GEX
(21 CFR §878-4810)

Legally Marketed Predicate Devices:

- Candela, Inc. - Gentle YAG Laser System (K022951)
- Fotona d.d. - XP Nd:YAG Laser System (K090126)
- Cynosure, Inc. - Apogee Elite Laser (K034030)

Section 4
510(k) Summary Statement
Hyperion Long Pulsed Nd:YAG Laser

- Intended Use of Hyperion: Hyperion is a long pulsed Nd:YAG laser intended for treatment of wrinkles, Removal of unwanted hair for stable long term or *permanent hair reduction, treatment of *pseudofolliculitis barbae* (PFB), surgical incision, excision, vaporization, ablation and coagulation of soft tissue, and photocoagulation and hemostasis of pigmented and vascular lesions in dermatology. *Permanent hair reduction is defined as the long-term stable reduction in the number of hairs re-grown when measured at 6, 9, and 12 months after the completion of a treatment regimen
- Device Description: Hyperion is a long pulse Nd:YAG laser system that produces laser emission at the wavelength of 1064nm. The system consists of three interconnected sections: a) the main cabinet, which houses the power supply, cooling system, microprocessor, and the laser generator, b) the optical fiber with hand pieces which can be used selectively depending on the size of the laser beam exposure, c) the footswitch.
- Performance Data: Non-clinical testing of Hyperion included visual and mechanical inspection, electrical and mechanical safety testing, software testing, etc., in bench. Electrical testing was performed in accordance with IEC 60601-1 and 60601-1-2 standards.
- Substantial Equivalence (Intended Use) Hyperion's intended use is identical to the intended use of the predicate devices: *Candela's Gentle YAG Laser System, Fotona's XP Nd:YAG Laser System, and Cynosure's Apogee Elite Laser*
- Substantial Equivalence (Technical) Hyperion is based on the Nd:YAG (1064 nm) laser technology as its predicated devices listed above. Hyperion long pulsed Nd:YAG laser operates in a similar fashion as its predicate devices, with the same principle of operation, the same wavelength (1064 nm) and essentially the same power range and the same indications for uses.
- Based upon analysis of the overall performance characteristic for the device, Laseroptek Co. Ltd. believes that no significant differences exist between Hyperion and its predicate devices. Therefore, Hyperion should not raise new safety or effectiveness issues.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Laseroptek Company, Ltd
% Mr. Kevin J. Choi
Scarlet RF Incorporated
28 Stafford Drive
West Windsor, New Jersey 08550

January 22, 2014

Re: K132286

Trade/Device Name: Hyperion Long Pulse Nd: YAG Laser
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 24, 2013
Received: December 27, 2013

Dear Mr. Choi:

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  Mopper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
For Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K132286

Device Name
Hyperion Long Pulse Nd: YAG Laser

Indications for Use (Describe)
Treatment of wrinkles
Removal of unwanted hair for stable long term or *permanent hair reduction
Treatment of PFB (pseudofolliculitis barbae)
Surgical incision, excision vaporization, ablation and coagulation of soft tissue
Photocoagulation and hemostasis of pigmented and vascular lesions in dermatology

*Permanent hair reduction is defined as the long-term stable reduction in the number of hair re-grown when measured at 6, 9, and 12 months after the completion of a treatment regimen.

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
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