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510(k) SUMMARY

Aerolase Model Nd:YAG 1064nm Laser

SEP 17 2012

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Aerolase Corporation/Aerolase Medical LLC (formerly Innotech USA, Inc.)
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Date Prepared: September 7, 2012

Device Trade Names and Name/Address of Sponsor

Aerolase Model Nd:YAG 1064nm Laser: FriendlyLight Nd:YAG, FriendlyLight Neo™, LightPod®ND:YAG™, LightPod® Neo™, LightPod® Forte™, LightPod® Allure™, LightPod® Nova™

Common or Usual Name

Nd:YAG Laser

Classification Name

Powered, Surgical Laser Instrument (21 C.F.R. §878.4810)

Predicate Devices

Innotech USA, , The FriendlyLight® Nd:YAG Lasers (K033251)
Cutera, Inc., Cutera GenesisPlus Laser System (K103626)
Incisive, Inc., PinPointe™ FootLaser™ Nd:YAG Lasers (K093545, K093547)
Fotona d.d., Fotona XP / Dynamis Nd:YAG Laser Systems (K090126, K101306)

Intended Use / Indications for Use

The Aerolase Nd:YAG Laser is intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laparoscopic general surgery, gastroenterology, gynecology, otolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery, podiatry, and urology for surgical and aesthetic applications.

Dermatology:

The Aerolase Nd:YAG Laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions, such as warts, scars, striae, debridement of decubitus ulcer, treatment of keloids, and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to,

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lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

Additionally, the Aerolase Nd:YAG Laser is indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

The Aerolase Nd:YAG Laser is also indicated for the treatment of wrinkles, such as, but not limited to, periocular and perioral wrinkles.

The Aerolase Nd:YAG Laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

The Aerolase Nd:YAG Laser is also indicated for treatment of mild to moderate inflammatory acne vulgaris.

The Aerolase Nd:YAG Laser is also indicated for the removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB). Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

The Aerolase Nd:YAG Laser is indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

Podiatry:

Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue), including:

- Matrixectomy;
- Periungual and subungual warts;
- Plantar warts;
- Radical nail excision;
- Neuromas.

General Surgery:

The Aerolase Nd:YAG Laser is indicated for the incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in the performance of surgical applications in endoscopy/laparoscopy gastroenterology, general surgery, head and neck/otolaryngology (ENT) neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/ thoracic surgery, gynecology (e.g. menorrhagia), podiatry and urology. All soft tissue is included, striated and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Technological Characteristics/Principles of Operation

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The Aerolase Nd:YAG 1064nm Laser is Neodymium doped Yttrium-Aluminum-Garnet ("Nd:YAG") Laser. This device consists of the following components and accessories: a power supply unit with an air-cooling system, and a laser hand piece connected to the power supply/air cooling system using umbilical cords. Laser parameters are controlled from a display panel located on the front of the power supply unit.

Performance Data

Product testing was performed to confirm compliance with the following standards: 21 C.F.R. 1040, IEC-60601-1, IEC-60601-2, IEC-60601-2-22, and IEC-60825-1. In all instances, the Aerolase 1064nm Laser functioned as intended and results observed were as expected. In addition, published clinical data supports the safe and effective use of this device.

Substantial Equivalence

The Aerolase Nd:YAG 1064nm Laser is as safe and effective as the identified predicate devices listed above. The Aerolase Nd:YAG 1064nm Laser has the same intended uses / indications for use, technological characteristics, and principles of operation as its predicate devices. Performance data demonstrate that the Aerolase Nd:YAG 1064nm Laser is as safe and effective as the predicate devices. Thus, the Aerolase Nd:YAG 1064nm Laser is substantially equivalent.



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

Aerolase Medical Lasers, LLC
% Hogan Lovells US LLP
Ms. Jennifer A. Henderson
Regulatory Counsel
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

SEP 17 2012

Re: K120235

Trade/Device Name: Aerolase Model Nd:YAG 1064nm Laser (Trade Names: FriendlyLight Nd: YAG, FriendlyLight Neo™, LightPod® ND:YAG™, LightPod® Neo™, LightPod® Forte™, LightPod® Allure™, LightPod® Nova™)

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: September 13, 2012

Received: September 14, 2012

Dear Ms. Henderson:

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.

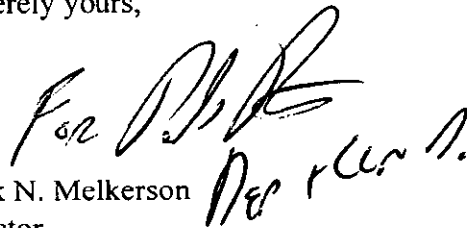
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

Indications for Use Statement

510(k) Number (if known): K120235

Device Name: Aerolase Model Nd:YAG 1064nm Laser (Trade Names: FriendlyLight Nd:YAG, FriendlyLight Neo™, LightPod®ND:YAG™, LightPod® Neo™, LightPod® Forte™, LightPod® Allure™, LightPod® Nova™)

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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)

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

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