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Section 10
510(k) Summary

This 510(k) summary of safety and effectiveness for the Focus Medical NaturaLase LP and NaturaLight Family of Products is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: Focus Medical

Address:
Focus Medical, LLC
23 Francis J. Clarke Circle
Bethel, CT 06801

Contact Person: Mr. John B. Lee, Jr.
President
Focus Medical

Telephone: 203-730-8885

Preparation Date: June 2004
(of the Summary)

Device Name:
NaturaLase LP and NaturaLight Family of Products

Common Name:
Nd:YAG and Intense Pulsed Light treatment system

Classification:
Laser surgical instrument for use in general and plastic surgery and in dermatology.

Class II medical device
21CFR 878.4810
Product Code: GEX
Panel: 79

Predicate devices:
Palomar Starlux Pulsed Light System (K033549)
Lumenis Family of Intense Pulsed Light (IPL) and IPL/Nd:YAG Laser Systems (K030527)
Lumenis IPL Quantum Family of Products (K020839)
Focus Medical NaturaLase LP (K031828)

Device description:
The Focus Medical NaturaLase LP and NaturaLight Family of Products consists of the NaturaLase LP Nd:YAG Laser System, the NaturaLight IPL System and the NaturaLase LP+ a simple combination of the NaturaLase LP and the NaturaLight.

Indications for Use:

NaturaLight Indications for Use

NaturaLight IPL System and the NaturaLase LP+ System when used in IPL (intense pulsed light) Mode is indicated for:

Dermatology/Plastic Surgery:

The removal of unwanted hair from skin types I-VI, and to effect stable long-term, or permanent, hair reduction.
The treatment of benign pigmented lesions, including lentigines, nevi, melasma, and cafe-au-lait. treatment of vascular lesions, including port wine stains, hemangiomas, angiomas, telangiectasias, rosacea, facial and leg veins.

NaturaLase LP Indications For Use

The Focus Medical NaturaLase LP Laser System and the NaturaLase LP+ System when used in Laser Mode is indicated for:

General Surgical Applications:

Incision, excision, coagulation, hemostasis, vaporization, and/or ablation of soft tissue in dermatology/plastic surgery, endoscopic/laparoscopic general surgery, gastroenterology, general surgery, gynecology, head and neck/ otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary surgery, thoracic surgery, and urology.

Dermatology/Plastic Surgery:

Coagulation and hemostasis of benign vascular lesions such as port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg and spider veins. In addition, the NaturaLase LP is intended for the treatment of benign pigmented lesions such as, but not limited to, 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.
The NaturaLase LP Laser is also 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.
Cutting, incision, excision, hemostasis, coagulation, vaporization and ablation of soft tissue in dermatology and plastic surgery.
The NaturaLase LP Laser is also indicated for the treatment of facial wrinkles and wrinkles such as, but not limited to, periocular and periorbital wrinkles.
The NaturaLase LP Laser is indicated for the removal of unwanted hair, for the stable long tem, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB).

The NaturaLase LP Laser is indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
The NaturaLase LP Laser is indicated for use on all skin types (Fitzpatrick I - VI) including tanned skin.

Endoscopic/Laparoscopic Surgery:
The NaturaLase LP Laser is also indicated for use in a variety of surgical procedures in several surgical specialties. These include, but not limited to, cholecystectomy, appendectomy, vagotomy, and pyloromyomotomy where its abilities to incise, excise, coagulate, vaporize, or ablate soft tissue may be applied.

Gastroenterology:
Tissue ablation and hemostasis in the gastrointestinal tract; esophageal neoplastic obstruction including squamous cell carcinoma and adenocarcinoma, gastrointestinal hemostasis including varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers, gastric erosions, gastrointestinal tissue ablation including benign and malignant neoplasm, angiodysplasia, polyps, ulcer, colitis, and hemorrhoids.

General Surgery:
Incision, excision, vaporization, ablation, and hemostasis of soft tissue general surgery applications, skin incisions, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors, lesions, tissue ablation, vessel coagulation, tonsillectomy, and hemorrhoids.

Gynecology:
Treatment of menorrhagia by photocoagulation of the endometrial lining of the uterus, ablation of endometrial implants and/or peritoneal adhesions, soft tissue excisional procedures such as excisional conization of the cervix, intrauterine gynecologic procedures where cutting, ablation, and/or vessel coagulation may be indicated including submucous fibroids, benign endometrial polyps, and uterine septum.

Head and Neck/Otorhinolaryngology (ENT):
Tissue incision, excision, ablation, and vessel hemostasis.

Hemostasis During Surgery:
Adjunctive coagulation and hemostasis (bleeding control) during surgery in endoscopic (e.g. laparoscopic) and open procedures.

Neurosurgery:
Hemostasis for pituitary tumor, meningioma, hemagioblastoma, AVMs. glioblastoma, astrocytoma, oligodendroglioma.

Oculoplastics:
Incision, excision, vaporization, and/or coagulation of tissues in oculoplastic procedures such as operations on the lacrimal system, operation on the eyelids, removal of biopsy or orbital tumors, enucleation on eyeball, exteneration of orbital contents.

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Orthopedics:
Cutting, ablation, and/or hemostasis of intra-articular tissue in orthopedic surgical and arthroscopic applications.

Pulmonary Surgery:
Palliative treatment of benign and malignant pulmonary airway obstructions, including squamous cell carcinoma, adenocarcinoma, carcinoid, benign tumors, granulomas, and benign strictures.

Thoracic Surgery:
Cutting (incision/excision), coagulating, and vaporization of soft tissue. Thoracic applications including, but not limited to, isolation of vessels for endarterectomy and/or by-pass grafts, wedge resections, thoractomy, formation of pacemaker pockets; vaporization, coagulation, incision/excision, debulking, and ablation of lung tissue (thoracoscopy).

Urology:
All applications including superficial urinary bladder tumors, invasive bladder carcinoma, urethral strictures and lesions of the external genitalia (including condyloma acuminata).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2004

Mr. John B. Lee, Jr.
President
Focus Medical, LLC
23 Francis J Clarke Circle
Bethel, Connecticut 06801

Re: K041829
Trade/Device Name: NaturaLase LP and NaturaLight Family of Products
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: July 7, 2004
Received: July 12, 2004

Dear Mr. Lee:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):K041829

Device Name:

Indications For Use:

NaturaLight IPL System (intense pulsed light) is indicated for:
The removal of unwanted hair from skin types I-VI, and to effect stable long-term, or permanent, hair reduction. The treatment of benign pigmented lesions, including lentigines, nevi, melasma, and cafe-au-lait. treatment of vascular lesions, including port wine stains, hemangiomas, angiomas, telangiectasias, rosacea, facial and leg veins.

NaturaLase LP Indications For Use
The Focus Medical NaturaLase LP Laser System and the NaturaLase LP+ System when used in Laser Mode is indicated for:

General Surgical Applications:
Incision, excision, coagulation, hemostasis, vaporization, and/or ablation of soft tissue in dermatology/plastic surgery, endoscopic/laparoscopic general surgery, gastroenterology, general surgery, gynecology, head and neck/ otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary surgery, thoracic surgery, and urology.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041829

Dermatology/Plastic Surgery:

Coagulation and hemostasis of benign vascular lesions such as port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg and spider veins. In addition, the NaturaLase LP is intended for the treatment of benign pigmented lesions such as, but not limited to, 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.
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