MAR - 2 2004

K 033251 1/3 Attachment 11

510(k) Summary
The FriendlyLight® Nd:YAG Lasers

Submitted by:

Innotech USA, Inc.
FriendlyLight® Aesthetic Lasers Division
777 Old Saw Mill River Road, Suite 205
Tarrytown, NY 10591

October 2, 2003

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Contact Person: Howard M. Holstein, Esq., Partner
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2. Device Name and Classification:

Trade Name:	The FriendlyLight® Nd:YAG Lasers
Classification Name:	Laser instrument, surgical, powered
Common Name:	Neodymium doped Yttrium-Aluminum-Garnet Laser
Classification Panel:	General and Plastic Surgery: Panel 79
CFR Section:	21 CFR §878.4810
Device Class:	Class II

3. Substantial Equivalence:

The **FriendlyLight® Nd:YAG Lasers** are substantially equivalent to the current, legally marketed **Family of Altus Medical CoolGlide® Aesthetic Lasers (k022226), Palomar Q-YAG Nd:YAG Laser System (k023967), Candela Long Pulse Nd:YAG Laser (k010104) and GentleYAG Laser System (k022951), Continuum Medical Laser System (k970808 and k014234), CoolTouch "Varia" and "Varia-II" Nd:YAG Surgical Laser Systems (k010316),**

Cosmos Medical Athos Long Pulse Nd:YAG laser (k001704), Laserscope's Lyra Surgical Laser System & Accessories (Nd:YAG configuration) (k990903 and k020021), Sciton Image Hair Removal Nd:YAG Laser (k012552). The **FriendlyLight® Nd:YAG Lasers** have the same intended use and general and specific indications as the predicated **CoolGlide®** devices. These devices have very similar principles of operation and technological characteristics. The minor technological differences do not raise any new questions of safety and effectiveness. Performance data demonstrates that **FriendlyLight® Nd:YAG Lasers** are as safe and effective as the predicated devices.

4. Device Description:

The FriendlyLight® Nd:YAG Laser consists of a power supply unit, an air-cooling system, a foot switch, and the hand piece that connects the laser unit and power supply/air-cooling system using an umbilical cord. In standard use, the hand piece is held against the treatment area and the light pulse is delivered when the foot switch and/or hand switch is depressed. Laser parameters and other system features are controlled from a display panel located on the front of the power supply unit.

5. Intended Use/Indications for Use:

The FriendlyLight® Nd:YAG Lasers are intended to be used in the medical specialties of general and plastic surgery, dermatology, endoscopic/laproscopic general surgery, gastroentermology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculaplastics, orthopedics, pulmonary/thoracic surgery and urology for surgical and aesthetic applications.

Dermatology:
The FriendlyLight® Nd:YAG Laser systems are 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, and psoriasis. The lasers are also 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.

Additionally, the lasers are 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 FriendlyLight® Nd:YAG Lasers are also indicated for the treatment of wrinkles, such as, but not limited to, periocular and perioral wrinkles.

The FriendlyLight® Nd:YAG Lasers are 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).

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

The FriendlyLight® Nd:YAG Lasers are indicated for use on all skin types (Fitzpatrick I-IV), including tanned skin.

Surgical Application:
The lasers are indicated for the incision/excision and cutting, ablation, coagulation/hemostatis of soft tissue in the performance of surgical applications in endoscopy/laproscopy gastroenterology, general surgery, head and neck/otorhinolaryngology (ENT) neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/ thoracic surgery, gynecology (e.g. menorrhagia) and urology.

6. Performance Data:

The **FriendlyLight® Nd:YAG** Lasers have been thoroughly tested according to international standards equivalent to the standard IEC 601. Results from the testing indicate that the device is as safe and effective as the predicate devices.

7. Conclusion:

The **FriendlyLight® Nd:YAG Lasers** are substantially equivalent to the current legally marketed **Family of Altus Medical CoolGlide® Aesthetic Lasers (k022226), Palomar Q-YAG Nd:YAG Laser System (k023967), Candela Long Pulse Nd:YAG (k010104) and GentleYAG Laser System (k022951), Continuum Medical Laser System (k970808 and k014234), CoolTouch "Varia" and "Varia-II" Nd:YAG Surgical Laser Systems (k010316), Cosmos Medical Athos Long Pulse Nd:YAG laser (k001704), Laserscope's Lyra Surgical Laser System & Accessories (Nd:YAG configuration) (k990903 and k020021), Sciton Image Hair Removal Nd:YAG Laser (k012552).**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2004

Innotech USA, Inc.
c/o Howard M. Holstein, Esq.
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, D.C. 20004-1109

Re: K033251
Trade/Device Name: FriendlyLight Nd:YAG Lasers
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: February 5, 2004
Received: February 5, 2004

Dear Mr. Holstein:

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

INNOTECH USA, INC.

INDICATIONS FOR USE STATEMENT

510(k) Number: ~~New Submission~~ K 033251

Device Name: FriendlyLight® Nd:YAG Lasers

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

Prescription Use ✓ **510(k) Number** K033257 Over-the-Counter Use _____
(per 21 CFR 801.109)

INNOTECH USA, INC., 777 OLD SAW MILL RIVER ROAD, SUITE 205, TARRYTOWN, NY 10591
TELEPHONE: (914) 345-8300 FAX: (914) 345-8303 E-MAIL: info@friendlylight.net

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

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

510(k) Number K033251

Prescription Use ✓ OR ~~Over-the-Counter~~ Use _____
(per 21 CFR 801.109)