

4-1-99

K990174

FISMA INC.,
3959 West 1820 South
Salt Lake City, Utah 84104
(801) 972-0500
(801) 972-4884 (fax)
Tracy S. Best, Regulatory Manager
Preparation Date: January 13, 1999

Summary of Safety and Effectiveness for the:

Trade Name: Elite Family of Lasers

Common Name: Diode Nd:YAG Frequency Doubled, 532 nm

Classification Name: Laser Instrument, Surgical Powered - 79GEX

Legally Marketed Predicate Devices for Substantial Equivalence:

*Iris Medical Instruments, Inc., DioLite 532 Laser System

*Continuum Biomedical, Inc., CB Diode/532 Laser System

*Laserscope, Aura KTP 532/Green.

Rationale for SE: The Elite Family Lasers and Delivery Devices share similar indications for use, and similar design features including; wavelengths, beam integrity, and cooling type. Control systems such as interlock devices, (safety systems) and displays are constantly monitored for user intervention. Functional features such as; delivery power, pulse rates, energy type, and spot sizes are also similar to the aforementioned devices. *Also see Attachment "A" Comparison Chart of Equivalence.*

Description of Submitted Device:

The Diode Frequency Doubled Green Nd:YAG Surgical Laser System is an instrument used in the application of Photothermolysis (Photocoagulation) of soft tissue using a 532 nm wavelength. The laser light is produced by diode technology. With a higher level of output power of up to 10.0 Watts on future models, additional indications for use are warranted. Indications for use are supported by a line of collimated handpieces with spot sizes of: 200, 400, 600, 800, and 1200 microns, as well as, Slit Lamps (M-140 & M-150), Slit Lamp Attachments, (M-100 & M-101), Indirect Ophthalmoscopes, and Microfilters (Fixed and Moving).

Intended Uses of the Elite Family Lasers:

See attachment "B" for a complete listing of indicated uses (applied for).

Technological Characteristics and Substantial Equivalence:

The Elite Family's primary energy output source is a Diode Pumped Nd:YAG Rod, Frequency Doubled using a KTP crystal to a visible green 532 nm laser light for the delivery to the patient and treatment. This system has various timing features for interval, and duration. The Aiming Beam is a Visible Red Diode @ 620-640 nm wavelength.

The Continuum Biomedical, Inc., CB/Diode/532 Laser System uses infrared (808 nm) semiconductor diode laser light as the primary source of energy and is then converted to a visible wavelength of 532 nm laser light. The CB Diode/532 Laser System delivers the same wavelength, similar power, spot sizes and pulses of equivalent duration to the Elite Family.

The Laserscope, Aura Laser System uses arc lamps as the primary form of energy to optically pump a Nd:YAG Rod, the output of which is wavelength converted to visible green 532 nm laser light for the delivery to the patient and treatment. The Aura Laser System delivers the same wavelength, similar average power, pulses of equivalent duration, and treatment spots of equivalent diameter.

The Iris Medical DioLite 532 is a semiconductor-based laser system which delivers 532 nm laser light. The DioLite uses an infrared (808 nm) semiconductor diode laser light as the primary source of energy which is then converted to visible green 532 nm for delivery to the patient and treatment. The system delivers similar average power, durations and intervals. Although the beginning wavelength is different, the final treatment beam to the patient is the same.

Conclusion:

The Elite Family Diode Pumped Green Nd:YAG Frequency Doubled Surgical Laser Systems are substantially equivalent to other existing surgical laser systems in commercial distribution.



APR 1 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tracy S. Best
Regulatory Manager
FISMA, Inc.
3959 West 1820 South
Salt Lake City, Utah 84104

Re: K990174
Trade Name: Elite Family of Lasers
Regulatory Class: II
Product Code: GEX
Dated: January 13, 1999
Received: January 19, 1999

Dear Mr. Best:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

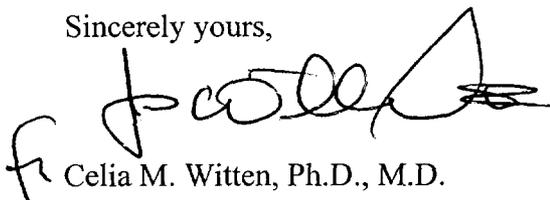
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. Tracy S. Best

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

Enclosure

510(k) Number (if known): K990174

Device Name: Elite Family Lasers (Detailed Below)

Indications For Use:

Ophthalmology:

(Atlas-Elite, Elite Ultra)

- ▶Retinal Photocoagulation
- ▶Trabeculoplasty
- ▶Iridotomy
- ▶Diabetic Retinopathy
- ▶Peripheral Iridectomy
- ▶Posterior and Anterior procedures

Ear, Nose, & Throat (ENT):

(Atlas-Elite, Elite Ultra)

- ▶Stapedectomy
- ▶Stapedotomy
- ▶Myringotomies
- ▶Lysis of Adhesions
- ▶Control of Bleeding
- ▶Removal of Acoustic Neuromas
- ▶Soft Tissue Adhesion in Micro/Macro Otologic procedures

(Elite Ultra [4.0 Watt] only)

- *Epistaxis (HHT)*
- *Partial Turbinate Reduction*
- *Vaporization/Coagulation of Granulation Tissue*
- *Photocoagulation or Vaporization of Soft or Fibrous Tissue*

Dermatology: (Atlas-Elite, Elite Ultra, Corium 200, & Corium 400)

- ▶Pigmented Lesions, inc. solar lentiginos
- ▶Vascular Lesions, inc. cherry hemangiomas & angiokeratomas
- ▶Extremities Telangiectasias, inc. facial & leg telangiectasias
- ▶Cutaneous Lesions
- ▶Flat Warts
- ▶Dermatosis
- ▶Papulosa Nigra

Dentistry

(Corium 200, Corium 400)

- ▶Frenectomy
- ▶Treatment of Oral Mucous Cysts
- ▶Treatment of Benign Vascular Lesions:
 - ▶Capillary Hemangioma
 - ▶Hemorrhagic Hereditary Telangiectasia
 - ▶Capillary/Cavernous Hemangiomas
 - ▶Lymphangioma
 - ▶AV Malformation of the Tongue
 - ▶Hemangiolympangiomas
- ▶Photocoagulation of Superficial Vessels
- ▶Vaporization of Superficial Blood Vessels or Lymphs Containing Vessels
- ▶Treatment of Superficial Tongue Lesions
- ▶Tissue Management and Hemostasis for Crown and Bridge Impressions
- ▶Incision and Drainage for Abscess
- ▶Gingivoplasty/Gingivectomy:
 - ▶Operative Procedures
 - ▶Crown and Bridge, Gingival Retraction
 - ▶Crown Lengthening
 - ▶Hyperplasia (Drug, Irritation, Epulis, ...)
- ▶Hemostasis during Dental Procedures
- ▶Operculectomy (Operculotomy)
- ▶Excisional Biopsy
- ▶Free Gingival Graft (Adjunct):
 - ▶Hemostasis of Donor Site
 - ▶Hemostasis of Graft Site
- ▶Vestibuloplasty
- ▶Soften Gutta Percha
- ▶Treatment of Canker Sores, Herpetic Lesions, and Aphthous Ulcers
- ▶Laser-assisted bleaching/whitening

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General Restorative Devices
510(k) Number

K 990174

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____