K 021548

Appendix E : Summary of Safety and Effectiveness Data

I. General Information

DEC 0 6 2002

Company :	**Fotona d.d.** **Stegne 7, 1210 Ljubljana** **SLOVENIA**
Contact Person :	**Mojca Valjavec**
Preparation Date :	**05-03-02**
Device Trade Names :	**Fotona Dualis^{SP} Nd:YAG/Er:YAG Laser System**
Common Name :	**Combination of Long Pulse Nd:YAG and Er:YAG Lasers**
Classification Name :	**Instrument, Surgical, Powered, Laser** 79-GEX **21 CFR 878-48**

II. Description

The Fotona Dualis^{SP} laser system is based on the Nd:YAG (1064 nm) and Er:YAG (2940 nm) laser technology. It is modification to combine two lasers into one housing. The unmodified devices are the Fotona Fidelis Er:YAG laser and the Fotona Dualis^{XP} Nd:YAG laser system. There are two optical cavities containing the Nd:YAG and Er:YAG crystals. Both are activated by means of the use of flashlamps. After each cavity, a red diode aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly. The combined therapeutic and aiming beams are guided:

- In case of the Nd:YAG laser through an optical fiber delivery system to a focusing handpiece.
- In case of the Er:YAG laser through articulated arm to a focusing handpiece.

Both lasers share a common power supply, control system, and cooling system. The internal computer can be directed to select either the Er:YAG laser source or the Nd:YAG laser source. When the laser is first turned on the physician is able to select the desired wavelength via control panel.

III. Intended Use

The Fotona Dualis^{SP} Nd:YAG laser is indicated for use in surgical and aesthetic applications requiring selective photothermolysis of target chromophores in soft tissue in general and plastic surgery and dermatology. In addition, the family is indicated to effect stable long-term, or permanent hair reduction in Fitzpatrick skin types I - VI through

Attachment 4

selective targeting of melanin in hair follicles (where permanent hair reduction is defined as a long-term stable reduction in number of hairs regrowing after a treatment regimen). The Fotona Dualis^{SP} Er:YAG laser is indicated for incision/excision, cutting, ablation, vaporization, and coagulation of soft and hard tissue in various surgical areas.

IV. Summary of Substantial Equivalence

Fotona believes that its Dualis^{SP} laser system is substantially equivalent to the Fotona Dualis^{XP} long pulse Nd:YAG laser system previously cleared for incision, ablation, vaporization, and coagulation of soft tissue in various surgical areas, and for permanent hair reduction in Fitzpatrick skin types I – VI, and to the Fotona Fidelis Er:YAG laser system previously cleared for incision/excision, cutting, ablation, vaporization, and coagulation of soft and hard tissue in various surgical areas.

They therefore have the same Intended Use as the Fotona Dualis^{SP} laser system.

The Dualis^{SP} Nd:YAG/Er:YAG laser system shares the same design features (wavelength, active medium, cooling system, power supply, beam deliveries, controls, housing) as the predicate devices. The output characteristics are the same as those of the predicate devices.

The risk and benefits for the Dualis^{SP} laser system are comparable to the predicate devices when used for similar clinical applications.

It is therefore believed that there are no new questions of Safety or Effectiveness raised by the introduction of the Dualis^{SP} Nd:YAG/Er:YAG laser system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2002

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Slovenia

Re: K021548
Trade/Device Name: Fotona Dualis Nd:YAG/Er:YAG Laser System and Accessories
Regulation Number: 878.4810
Regulation Name: Instrument, surgical powered laser
Regulatory Class: Class II
Product Code: GEX
Dated: October 18, 2002
Received: October 18, 2002

Dear Sir or Madam:

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. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

Appendix F : Indications for Use Statement

510(k) Number (if known): K 021548

Device Name: **Fotona Dualis^{SP} Nd:YAG/Er:YAG Laser System and Accessories**

Indications For Use:

Nd:YAG Laser (1064 nm)

The Fotona Dualis^{SP} Nd:YAG laser is intended for incision, ablation, vaporization, and coagulation and hemostasis of vascular lesions and soft tissue in various surgical areas, and for permanent reduction of unwanted hair in Fitzpatrick skin types I - VI.

Dermatology: Coagulation and hemostasis of vascular lesions, and To effect stable long-term, or permanent, hair reduction in skin types I - VI through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen.

Plastic Surgery: Coagulation and vaporization of soft tissue.

Otorinolaryngology /Head and Neck (ENT): Tissue ablation and vessel hemostasis.

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

Orthopedics: Ablation, vaporization, incision, excision, coagulation, and hemostasis of soft and cartilaginous tissue in small and large joints including but not limited to knee menisectomy, knee synovectomy, chondromaliacia and tears, shoulder debridement of scar tissue, and synovectomy of the shoulder.

Neurosurgery: hemostasis in neurosurgery procedures such as excision of brain lesions, spinal cord lesions cranial nerves, peripheral nerves, and pituitary glands.

Gastroenterology: Tissue ablation and hemostasis in the gastrointestinal tract, cshophageal neoplastic obstructions including squamous cell carcinoma and adenocarcinoma;
Gastrintestinal hemostatsis including varices, espohagitis, esopageat ulcer, Mallory-Weiss tear, gastric ulcer, stomac ulcers, angiodysplasia, non-bleeding ulcers, gastric erosions;
Gastrintestinal tissue ablation including benign and malignant neoplasm, angiodysplasia, polyps, ulcer, colitis, hemorroids.

Er:YAG Laser (2940 nm)

The Fotona Dualis^{SP} Er:YAG laser is intended for surgical incision/excision, vaporization and coagulation of soft and hard tissue. All soft tissue is included, such as skin, subcutaneous tissue, striated and smooth tissue, cartilage meniscus, muscle, mucous membrane, lymph vessels and nodes, organs and glands.

Dermatology an Plastic Surgery Indications: Epidermal nevi, telangiectasias, spider veins, actinic sheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, decubitis ulcers, and skin resurfacing.

ENT Surgery Indications: ENT lesions, cysts, polyps, hyperkeratosis, oral leukoplakia

Gynecology Indications: Herpes simplex, endomaterial adhesion, CIN (Cervical intraepithelial neoplasia), cysts, and condiloma.

General Surgery Indications: Surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of lesions, complete or partial resection of internal organs, lesions, tissue ablation and vessel coagulation.

Oral/Maxillofacial Indications: Oral and glossal lesions and gingivectomy

Ophtalmology Indications: Soft tissue surrounding the eye and orbit and anterior capsulotomy

Podiatry Indications: Warts, plantar verrucae, large mosaic verrucae and matrixectomy

Dentistry indications: Caries removal, cavity preparation, enamel etching

(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 K021548

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)