K 022837

Appendix E : Summary of Safety and Effectiveness Data

NOV 2 5 2002

I. General Information

Company :	**Fotona d.d.** **Stegne 7, 1210 Ljubljana** **SLOVENIA**
Contact Person :	**Mojca Valjavec**
Preparation Date :	**08-08-02**
Device Trade Names :	**Fotona Tandem Laser System**
Common Name :	**Combination of Long Pulse Nd:YAG and Nd:YAG/KTP Lasers**
Classification Name :	**Instrument, Surgical, Powered, Laser** **79-GEX** **21 CFR 878-48**

II. Description

The Fotona Tandem laser system is based on the Nd:YAG (1064 nm) and KTP (532 nm) laser technology. There are two optical cavities containing the Nd:YAG and KTP 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 through the optical fiber delivery systems to the focusing handpieces.

Both lasers are used in non-contact mode.

Both laser heads share a common power supply, control system, and cooling system. The internal computer can be directed to select either the Nd:YAG head or the KTP (mixed-wavelength 1064/532 nm) head. When the laser is first turned on the physician is able to select the desired wavelength via control panel.

III. Intended Use

The Fotona Tandem Laser System and Accessories is intended for incision, ablation, vaporization, coagulation, and hemostasis of vascular lesions and soft tissue in various surgical areas, and for permanent hair reduction in Fitzpatrick skin types I-VI.

IV. Summary of Substantial Equivalence

Fotona believes that its Tandem laser system is substantially equivalent to the Fotona Dualis^{VP} long pulse KTP laser system previously cleared for incision, ablation, vaporization, coagulation, and hemostasis of vascular lesions and soft tissue in various surgical areas, to the Fotona Dualis^{XP} Nd:YAG laser system previously cleared also for permanent hair reduction in Fitzpatrick skin types I – VI, and to the Palomar Clear Light Nd:YAG laser system, marketed under Palomar Q-YAG 5. Similar as the Fotona Tandem, the Palomar system incorporates dual wavelengths (1064 and 1064/532 nm) and has been cleared for treatment of vascular lesions and removal of hair.

They therefore have the same Intended Use as the Fotona Tandem laser system.

The Tandem laser system shares the same design features (wavelength, active medium, cooling system, power supply, beam deliveries, controls, housing) as the Fotona Dualis^{VP} and the Fotona Dualis^{XP}.

The risk and benefits for the Tandem 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 Tandem laser system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 5 2002

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Stegne 7, 1210 Ljubljana
Slovenia

Re: K022837
Trade/Device Name: Fotona Tandem Laser System
Regulation Number: 878.4810
Regulation Name: Instrument, surgical, powered, laser
Regulatory Class: Class II
Product Code: GEX
Dated: August 20, 2002
Received: August 27, 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

Appendix F : Indications for Use Statement

510(k) Number (if known): K022837

Device Name: **Fotona Tandem Nd:YAG/KTP Laser System and Accessories**

Indications For Use:

The Fotona Tandem Laser System and Accessories is intended for incision, ablation, vaporization, coagulation, and hemostasis of vascular lesions and soft tissue in various surgical areas, and for permanent hair reduction in Fitzpatrick skin types I-VI.

KTP Laser (532 + 1064 nm)

The Fotona Tandem KTP laser is intended for incision, ablation, vaporization, coagulation, and hemostasis of vascular lesions and soft tissue in various surgical areas. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands.

Dermatology :

The treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size) of the vascular lesions (Angiomas, Hemangiomas, Telangiectasia)

Nd:YAG Laser (1064 nm)

The Tandem Nd:YAG laser systems is indicated for use in surgical and aesthetic applications requiring selective photothermolysis of target chromophores in soft tissue in the medical specialities of general and plastic surgery and dermatology:

- 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.
- For removal of unwanted hair.
- For coagulation and hemostasis of vascular lesions.
- For incision/excision of soft body tissue in dermatology.
- For soft tissue general surgery applications - skin incision; tissue dissection; complete or partial resection of internal organs, tumors, lesions; tissue ablation; vessel coagulation.

(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 Gen[illegible] Restorative
and Neurological Devices

Prescription Use ✓ (Per 21 CFR 801.109) 510(k) Number OR K022837 Over-The-Counter Use ___