K011939

Appendix F : Summary of Safety and Effectiveness Data

I. General Information

DEC 2 7 2001

Company :	Fotona d.d. Stegne 7, 1210 Ljubljana, Slovenia
Contact Person :	Mojca Valjavec
Preparation Date :	06-11-01
Device Trade Name :	Fotona Dualis KTP (532 nm) Laser System and Accessories
Common Name :	Frequency Doubled Nd:YAG Pulsed Surgical Laser System
Classification Name :	Instrument, Surgical, Powered, Laser 79-GEX 21 CFR 878-4810

II. Description

The Fotona Dualis KTP (532 nm) system is based on Nd:YAG laser technology. Within the system, an optical cavity contains the Nd:YAG crystal, which is activated by means of the use of flashlamps. After the cavity, a red diode aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly. The combined therapuetic and aiming beams are guided down an optical fiber delivery system to a focusing handpiece. The laser is used in non-contact mode.

The Dualis KTP system is designed with 3 major sub-systems:

a) An optical delivery system, interfacing the energy from the laser to the patient via an optical fiber arm and a focusing handpiece.

b) An electronic power supply and interface circuitry.

c) An optical chamber containing laser rod and laser cavity optics.

II. Intended Use

The Fotona Dualis KTP (532 nm) laser system is indicated 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.

III. Summary of Substantial Equivalence

Fotona believes that its Dualis KTP (532 nm) system is substantially equivalent to the Coherent VersaPulse laser system, Laserscope Lyra laser system, and to other KTP (532 nm) lasers previously cleared for similar clinical applications.

All lasers are cleared for surgical 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.

Technologically, the predicate devices have identical characteristics to the Dualis KTP (532 nm) laser, all three comprising an electronic control module and a flashlamp pumped Nd:YAG laser rod generating light at a wavelength of 532 μm, which is subsequently delivered to the patient via an optical fiber and a focusing handpiece.

The Dualis KTP (532 nm) laser output characteristics are very similar to those of the predicate devices.

All lasers are microprocessor controlled devices.

All lasers utilize class I aiming beams which pose no hazard to the user.

All systems utilize an internal closed loop water-air heat exchanger circuit for optimal thermal control of the laser cavity.

The risk and benefits for the Fotona Dualis KTP (532 nm) 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 this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2001

Mojca Valjavec
Fotona D. D.
Stegne 7
1210 Ljubljana
Slovenia

Re: K011939
Trade Name: Fotona Dualis
Regulation Number: 878.4810
Regulation Name: Instrument, Surgical, Powered, Laser
Regulatory Class: II
Product Code: GEX
Dated: October 11, 2001
Received: October 11, 2001

Dear Ms. Valjavec:

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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) 6382041 or (301) 4436597 or at its Internet address HYPERLINK http://www.fda.gov/cdrh/dsma/dsmamain.html http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

APPENDIX F

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K011939

Device Name: **FOTONA DUALIS KTP (532 nm) LASER SYSTEM AND ACCESSORIES**

Indications For Use:

The Fotona Dualis KTP (532 nm) Laser System and Accessories 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)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

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

510(k) Number K011939