Appendix E : Summary of Safety and Effectiveness Data

I. General Information

FEB 16 2006

K053139

Company : **Fotona d.d.**
Stegne 7, 1210 Ljubljana
SLOVENIA

Contact Person : Stojan Trošt

Preparation Date : **11-04-05**

Device Trade Names : **Fotona QX Nd:YAG/KTP Laser System**

Common Name : **Combination of Q-switched Nd:YAG and KTP Nd:YAG Lasers**

Classification Name : **Instrument, Surgical, Powered, Laser**
79-GEX
21 CFR 878-48

II. Description

The Fotona QX laser system is based on the Nd:YAG (1064 nm) and frequency doubled KTP Nd:YAG (532 nm) laser technology. There is one optical cavity containing the Nd:YAG crystal. The frequency doubled KTP Nd:YAG wavelength is achieved by directing the Nd:YAG laser beam through a frequency doubling non-linear crystal. The Nd:YAG laser 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 therapeutic and aiming beams are guided by articulated arm to a focusing handpiece. Both lasers are used in non-contact mode.

Both laser wavelengths 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 Nd:YAG laser wavelength. When the laser is first turned on the physician is able to select the desired wavelength via control panel.

The Fotona QX laser system consists of:

a) A high voltage power supply, which converts and rectifies the a.c. mains current to provide regulated power for the flashlamp simmer current and main triggering pulse.

b) A cooling system consisting of an internal water flow circuit together with water-to-air heat exchanger.

c) The microprocessor based controller, which regulates the functions of both lasers and allows parameter selection by the user.

d) The Nd:YAG laser head.

e) The frequency doubling crystal.

g) The optical delivery system, interfacing the energy from the laser to the patient via an articulated arm and focusing handpiece.

III. Intended Use

The Nd:YAG (1064 nm) laser is capable of delivering up to 1.0 J of laser energy. Its nominal pulsewidth is 4-9 nanoseconds. Spot sizes available range from 2 to 8 mm. This laser wavelength is intended to be used for incision/excision, ablation, vaporization of soft tissue in general dermatology, removal of dark ink (black, blue and brown) tattoos, treatment of Nevus of Ota, removal or lightening of unwanted hair, treatment of Common Nevi.

The frequency doubled Nd:YAG (532 nm) KTP laser delivers up to 0.5J of laser energy in 4-9 nanosecond pulses. Spot sizes available range from 2 to 7 mm. This laser wavelength is intended to be used for incision/excision, ablation, vaporization of soft tissue in general dermatology, removal of light ink (red, tan, purple, and orange) tatoos, removal of pigmented lesions, removal of vascular lesions, treatment of Lentigines, treatment of Cafe-Au-Lait, treatment of Common Nevi, treatment of Seborrheic Kearotoses, and treatment of Post Inflammatory Hyperpigmentation.

IV. Summary of Substantial Equivalence

Fotona believes that its Fotona QX laser system is substantially equivalent to the

a) Spectra -VRM Q-switched Nd:YAG Laser System (K000317) previously cleared for:

- Incision, excision, ablation, vaporization of soft tissue for general dermatology
- 532 nm wavelength:
  - removal of light ink (red, tan, purple, and orange) tatoos,
  - removal of pigmented lesions, removal of vascular lesions,
  - treatment of Lentigines, treatment of Cafe-Au-Lait,
  - treatment of Common Nevi,
  - treatment of Seborrheic Kearotoses,
  - treatment of Post Inflammatory Hyperpigmentation.

- 1064 nm wavelength:
  - removal of dark ink (black, blue and brown) tattoos,
  - treatment of Nevus of Ota,
  - removal or lightening of unwanted hair,
  - treatment of Common Nevi.

b) Medlite C6 Q-Switched Nd:YAG Laser (K 014234) previously cleared for incision, excision, ablation, vaporization of soft tissue for general dermatology, Tatoo removal, treatment of Vascular Lesions and treatment of Pigmented Lesions.

c) Palomar Q-YAG Nd:YAG Laser System (K023967) previously cleared for skin resurfacing with or without adjuvant preparation at the 1064 nm wavelength.

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

The Fotona QX 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 Fotona QX 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 Fotona QX Nd:YAG/KTP laser system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2006

Mr. Stojan Trost
Manager
Quality Assurance & Regulatory Affairs
Fotona D.D.
Stegne 7
1210 Ljubljana
SLOVENIA

Re: K053139
Trade/Device Name: Fotona QX Nd:YAG/KTP Laser System
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: January 5, 2006
Received: January 9, 2006

Dear Mr. Trost:

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting 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): K053139

Device Name: **Fotona QX Nd:YAG/KTP Laser System**

Indications For Use:

1. Incision, excision, ablation, vaporization of soft tissue for general dermatology.

2. 532 nm wavelength:
   - removal of light ink (red, tan, purple, and orange) tatoos,
   - removal of pigmented lesions, removal of vascular lesions,
   - treatment of Lentigines, treatment of Cafe-Au-Lait,
   - treatment of Common Nevi,
   - treatment of Seborrheic Kearotoses,
   - treatment of Post Inflammatory Hyperpigmentation.

3. 1064 nm wavelength:
   - removal of dark ink (black, blue and brown) tattoos,
   - treatment of Nevus of Ota,
   - removal or lightening of unwanted hair,
   - treatment of Common Nevi.
   - skin resurfacing with or without adjuvant preparation

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number _____