JUL 2 7 2000

K001527

Appendix E : Summary of Safety and Effectiveness Data

I. General Information

Company :	**Fotona d.d.** **Stegne 7, 1210 Ljubljana, Slovenia**
Contact Person :	**Mojca Valjavec**
Preparation Date :	**05-08-00**
Device Trade Name :	**Fotona Fidelis Er:YAG Laser System and Accessories**
Common Name :	**Er:YAG Laser System**
Classification Name :	**Instrument, Surgical, Powered, Laser** **79 - GEX** **21 CFR 878.48**

II. Description

The Fotona Fidelis system is based on Er:YAG laser technology. Within the system, an optical cavity contains the Er: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 therapeutic and aiming beams are guided down an articulated arm delivery system to a fiber tip handpiece. The laser is used in contact mode.

The System is capable of emitting up to 400 mJ of pulsed light at 2.94 æm when used for dental hard tissue applications.. This light has a pulsewidth which varies in the range 75 - 950 æs. The laser is intended to be used for incisions, excisions, vaporization, ablation and coagulation of soft and hard tissue in the mouth. The procedures include caries removal, cavity preparation and enamel etching. ←

The Fidelis system is designed with 5 major sub-systems:

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) An Er:YAG laser rod, capable of generating 400 mJ when used for dental hard tissue applications..

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

e) The microprocessor based controller which regulates the functions of the laser and allows parameter selection by the user.

III. Summary of Substantial Equivalence

Fotona believes that its Fidelis system is substantially equivalent to the Centauri (Premier Laser Systems (K932683 and K933841).

The Centauri is cleared for incisions, excisions, vaporization, ablation and coagulation of soft and hard tissue in the mouth. The procedures include caries removal, cavity preparation and enamel etching. ←

Technologically, the predicate device have identical characteristics to the Fidelis, both comprising a flashlamp pumped Er:YAG laser rod generating light at a wavelength of 2.94 æm, which is subsequently delivered to the patient either via an articulated delivery arm and fiber tip handpiece (Fotona Fidelis) or via sapphire fiber delivery system and fiber tip handpiece (Premier Centauri).

The risk and benefits for the Fotona Fidelis are comparable to the Premier Centauri when used for similar clinical applications.

The Premier Centauri has the ability to deliver laser energy at 2.94 microns, maximum output energy of 350 mJ and maximum repetition rate of 30 Hz. As the Fidelis has been designed also to be used for other applications (plastic surgery, dermatology, skin resurfacing) the maximum output energy is up to 1J and maximum repetition rate up to 50 Hz. When dental handpiece is used the output energy is limited to max. 400 mJ. The repetition rate is limited as well (max.20 Hz).

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

JUL 2 7 2000

Ms. Mojca Valjavec
Fotona d.d.
Stegne 7
1210 Ljubljana, Slovenia

Re: K001527
Trade Name: Fotona Fidelis Er:YAG Laser System
Regulatory Class: II
Product Code: GEX
Dated: May 8, 2000
Received: May 16, 2000

Dear Ms. Valjavec:

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 (Premarket 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.

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,

Donna R. Bochner.

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): K001527

Device Name: **FOTONA FIDELIS Er:YAG LASER SYSTEM**

Indications For Use:

The Fotona Fidelis Er:YAG Laser System is indicated to be used for incisions, excisions, vaporization, ablation and coagulation of soft and hard tissue in the mouth.

The procedures include caries removal, cavity preparation and enamel etching.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachuska

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001527

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