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Appendix E : Summary of Safety and Effectiveness Data

I. General Information

JUL 0 7 2003

Company :	**Fotona d.d.** **Stegne 7, 1210 Ljubljana** **SLOVENIA**
Contact Person :	**Mojca Valjavec**
Preparation Date :	**12-10-02**
Device Trade Names :	**Fotona Fidelis Plus Nd:YAG Laser System**
Common Name :	**Nd:YAG Laser**
Classification Name :	**Instrument, Surgical, Powered, Laser** **79-GEX** **21 CFR 878-48**

II. Description

The Fotona Fidelis Plus Nd:YAG system is a microprocessor controlled device which generates laser light with a wavelength of 1064 nm when used in conjunction with a host Fidelis Er:YAG system. When combined, the Nd:YAG (1064 nm) accessory and the host Er:YAG system constitute the Fidelis Plus laser system.

The Fotona Fidelis Plus Nd:YAG system is designed as an accessory for use with the Fotona Fidelis Er:YAG laser system. The Nd:YAG (1064 nm) sub-system is functionally integrated to the host laser system. When integrated, the host laser system recognizes the presence of the accessory and permits activation of the 1064 nm pulsed light via the same touchscreen as the host Er:YAG.

The Fidelis Plus Nd:YAG laser system consists of 3 major sub-systems:

a) An optical delivery system, interfacing the energy from the laser to the patient via an optical fiber and a handpiece.
b) An electronic power supply and interface circuitry.
c) An optical chamber containing laser rod and laser cavity optics.

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III. Intended Use

The Fotona Fidelis Plus Nd:YAG Laser System and Accessories is intended for incision, excision and coagulation of intraoral soft tissue, including the marginal and interdental gingiva. This includes incising, excising and coagulating the epithelium lining, the free or marginal gingiva, sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket).

IV. Summary of Substantial Equivalence

Fotona believes that its Fidelis Plus Nd:YAG laser system is substantially equivalent to the Sunlase 800P Nd:YAG laser system previously cleared for incision, excision and coagulation of intraoral soft tissue, including the marginal and interdental gingiva. It therefore has the same Intended Use as the Fotona Fidelis Plus Nd:YAG laser system..

Technologically, the predicate device has similar characteristics to the Fotona Fidelis Plus Nd:YAG, both comprising a flashlamp pumped Nd:YAG laser rod generating light at a wavelength of 1064 nm, which is subsequently delivered to the patient via an optical fiber delivery system and exits the proximal tip of the fiber.

The risk and benefits for the Fotona Fidelis Plus Nd:YAG 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 Fidelis Plus Nd:YAG laser system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Matjaz Lukac
President
Fotona d.d.
Stegne 7. 1210
Ljubjana, Slovenia

JUL 0 7 2003

Re: K024204
Trade/Device Name: Fotona Fidelis Plus Nd:YAG Laser System and Accessories
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: March 28, 2003
Received: April 9, 2003

Dear Mr. Lukac:

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) you may obtain. 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., 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): K024204

Device Name: **Fotona Fidelis Plus Nd:YAG Laser System and Accessories**

Indications For Use:

The Fotona Fidelis Plus Nd:YAG Laser System and Accessories is intended for incision, excision and coagulation of intraoral soft tissue, including the marginal and interdental gingiva. This includes incising, excising and coagulating the epithelium lining, the free or marginal gingiva, sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket).

- Excisional and incisional biopsies
- Excision and vaporization of herpex simplex I and II
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis
- Implant recovery
- Incision and drainage of abscess
- Laser assisted uvulopaletoplasty (LAUP)
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy and pulpotomy as an adjunct to root canal therapy
- Reduction of denture hyperplasia
- Reduction of gingival hypertrophy
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy
- Removal of post-surgical granulations
- Soft tissue crown lengthening
- Sulcular debridement or soft tissue curettage (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility)
- Tissue retraction for impression
- Treatment of apthous ulcers
- Vestibuloplasty

(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

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

510(k) Number K024204