Appendix E : Summary of Safety and Effectiveness Data

K990243

General Information and Description

JUN 9 1999

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 therapuetic and aiming beams are guided down an articulated arm delivery system to a focusing handpiece. The laser is used in non-contact mode.

The System is capable of emitting up to 1.0 J of pulsed light at 2.94 μm. This light has a pulsewidth which varies in the range 75 - 950 μs. The laser is intended to be used for surgical incision/excision, cutting, ablation, vaporization, and coagulation of soft tissue. 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.

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 1.0 J optical pulses at a frequency up to 50 Hz.

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

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

Accessories available for use with Fotona SkinPlus:

- Fotona SkinScan Scanning Device (K970757)

Summary of Substantial Equivalence

Fotona believes that its Fidelis system is substantially equivalent to the Laserscope Venus Erbium Laser System (EL Laser System) (K974896) and Laserscope Vela Erbium Laser System (K971843).

The Venus and Vela are cleared for surgical incision/excision, cutting, ablation, vaporization, and coagulation of soft tissue. 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. They therefore have the same Intended Use as the Fotona Fidelis.

Technologically, the predicate devices have identical characteristics to the Fidelis, all three comprising a flashlamp pumped Er:YAG laser rod generating light at a wavelength of 2.94 μm, which is subsequently delivered to the patient via an articulated delivery arm and focusing handpiece.

The risk and benefits for the Fotona Fidelis are comparable to the Laserscope Venus and Vela when used for similar clinical applications.

The Laserscope Venus Erbium Laser System has the ability to deliver laser energy at 2.94 microns, maximum power of 20 watts at repetition rate of up to 20 Hz. These characteristics are very similar to the Fotona Fidelis Erbium Laser System.

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

JUN 9 1999

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Stegne 7, 1210 Ljubljana
Slovenia

Re: K990243
Trade Name: Fotona Fidelis Er: YAG Laser System and Accessories
Regulatory Class: II
Product Code: GEX
Dated: April 26, 1999
Received: May 5, 1999

Dear Dr. Valjavec:

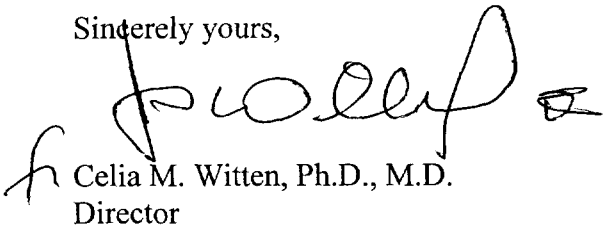
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K990243

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

Indications For Use:

The Fotona Fidelis Er:YAG Laser System and Accessories are intended for surgical incision/excision, cutting, ablation, vaporization, and coagulation of soft tissue. 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/Plastic Surgery : epidermal nevi, telangiectasia, spider veins, actinic chellitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision (including acne scars), debulking benign tumors and cysts, skin resurfacing, superficial skin lesions, and performing diagnostic biopsies.

General Surgery : surgical incision/excision, cutting, ablation, vaporization, and coagulation of soft tissue where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation and/or vessel coagulation may be indicated

Genitourinary : lesions of the external genitalia, urethra and anus, penis, scrotum and urethra, vulvar lesions, polyps and familial polyps of the colon

Gynecology : cerivecal intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma

Oral Surgery : benign oral tumors, oral and glossal lesions and gingivectomy, gingivoplasty, frenectomy, sulcular debridement - removal of diseased or inflamed soft tissue in the periodontal pocket ←

Otorhinolaryngology/Head and Neck (ENT) : ear, nose and throat lesions, polyps, cysts, hyperkeratosis, excision of carcinogenic tissue and oral leukoplakia

Ophthalmology : soft tissue surrounding the eye and orbit anterior capsulotomy

Podiatry : warts, plantar verrucae, large mosaic verrucae and matrixectomy

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990243

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