

AUG 10 1999

K991632

**Appendix E : Summary of Safety and Effectiveness Data****General Information and Description**

The Fotona Novalis Er:YAG system is a microprocessor controlled device which generates laser light with a wavelength of 2940 nm when used in conjunction with a host Novalis R system. When combined, the Er:YAG accessory and the host Ruby system constitute the Novalis RE laser system.

The Fotona Er:YAG system is designed as an accessory for use with the Fotona Novalis R laser system. The Er:YAG 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 2940 nm pulsed light via the same touchscreen as the host Ruby

The Novalis Er:YAG system is designed with 3 major sub-systems:

- d) An optical delivery system, interfacing the energy from the laser to the patient via an articulated arm and a focusing or collimated handpiece.
- b) An electronic power supply and interface circuitry.
- c) An optical chamber containing laser rod and laser cavity optics.

Accessories available for use with the Fotona Novalis Er:YAG:

- Fotona SkinScan Scanning Device

**Summary of Substantial Equivalence**

Fotona believes that its Novalis system is substantially equivalent to the Laserscope Venus Erbium Laser System (EL Laser System) and to the Continuum Biomedical (Con-Bio) CB Erbium/2.94 Er:YAG Laser.

Both lasers 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.

Technologically, the predicate devices have identical characteristics to the Novalis Er:YAG laser, all three comprising an electronic control module and a flashlamp pumped Er:YAG laser rod generating light at a wavelength of 2.94  $\mu\text{m}$ , which is subsequently delivered to the patient via an articulated delivery arm and focusing or collimated handpiece.

The risk and benefits for the Fotona Novalis are comparable to the Laserscope Venus Laser System and Continuum Biomedical (Con-Bio) CB Erbium/2.94 Er:YAG Laser System 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.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 10 1999

Ms. Mojca Valjavec, Dipl. Eng.  
Product Manager  
Lasers Division  
Fontona d.d.  
Stegne 7, 1210 Ljubljana, Slovenia

Re: K991632  
K991634

Trade Name: Fontona NovalisR Ruby Laser System  
Fontona Novalis Er:YAG Laser System

Regulatory Class: II

Product Code: GEX

Dated: May 3, 1999

Received: May 12, 1999

Dear Ms. Valjavec:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above, and we have determined the devices are 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 devices, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

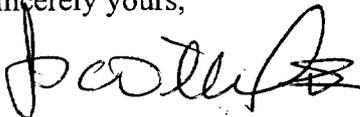
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 devices 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.

Page 2 – Ms. Mojca Valjavec, Dipl. Eng.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA, finding of substantial equivalence of your devices to legally marketed predicate devices, results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your devices 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) 594-4659. Additionally, for questions on the promotion and advertising of your devices, 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,

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

Enclosures

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K991632

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

Indications For Use:

The Fotona Novalis 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** : cerivcal intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma

**Oral/Maxillofacial** : benign oral tumors, oral and glossal lesions and gingivectomy

**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)

Prescription Use  (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K991632