

K980560

MAR 27 1998

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

The Fotona SkinPlus 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 focusing handpiece. The laser is used in non-contact mode.

The System is capable of emitting up to 2.0 J of pulsed light at 2.94  $\mu\text{m}$ . This light has a pulsewidth which varies in the range 100 - 500  $\mu\text{s}$ . The laser is intended to be used for cutting, ablating, vaporizing, coagulating of soft tissue, and skin resurfacing. ←

The SkinPlus 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 2.0 J optical pulses at a frequency up to 15 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)
- Fotona Skinlight Plus Nd:YAG System (K972368)

**Summary of Substantial Equivalence**

Fotona believes that its SkinPlus system is substantially equivalent to the Continuum Biomedical (Con-Bio) CB Erbium/2.94 Er:YAG laser (K970934) and is an upgrade of the the Fotona Skinlight laser system, previously cleared under K962902.

The CB Erbium/2.94 is cleared for skin resurfacing in the treatment of wrinkles, whereas the Skinlight is cleared for the cutting, ablation, vaporization, and coagulation of soft tissue. They therefore have the same Intended Use as the Fotona SkinPlus.

Technologically, the predicate devices have identical characteristics to the Fotona SkinPlus, both comprising a flashlamp pumped Er:YAG laser rod generating light at a wavelength of 2940 nm, which is subsequently delivered to the patient via an articulated arm and focusing handpiece.

The CB Erbium/2.94 and the Fotona SkinPlus have identical energy delivery capabilities and similar repetition rates. The SkinPlus and the Skinlight are sharing all characteristics except the energy level.

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

Ms. Mojca Valjavec, Dipl.Eng.  
Marketing and Sales Department  
Laser Division  
Fotona d.d.  
Stegne 7  
1210 Ljubljana, Slovenia

MAR 27 1998

Re: K980560  
Trade Name: Fotona SkinPlus Laser System  
Regulatory Class: II  
Product Code: GEX  
Dated: January 30, 1998  
Received: February 13, 1998

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.

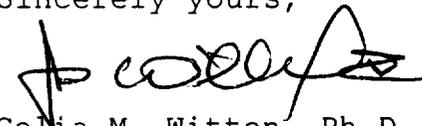
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Ms. Valjavec

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

# APPENDIX F

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510(k) Number (if known): K980560

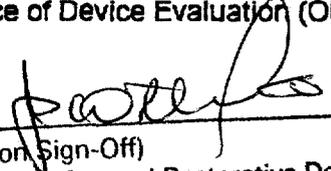
Device Name: FOTONA SKINPLUS LASER SYSTEM

**Indications For Use:**

*The Fotona SkinPlus Er:YAG surgical laser system is indicated for the cutting, ablation, vaporization, coagulation of soft tissue, and for skin resurfacing.* ←

(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 K980560  
510(k) Number \_\_\_\_\_

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)