Appendix E : Summary of Safety and Effectiveness Data

General Information and Description

The Fotona Skinlight Plus system is based on the addition of a Nd:YAG accessory to a previously cleared Er:YAG system (K962902). Within the accessory sub-system, an optical cavity contains the Nd: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 optical fiber delivery system to a focusing handpiece. The laser is used in non-contact mode.

The System is capable of emitting up to 2.0 Watts of light at 532 nm, with a minimal pulsewidth envelope of 100ms. The laser is intended to be used for the photocoagulation of benign vascular and pigmented lesions.

The Nd:YAG accessory sub-system is designed with 3 major sub-systems:

a) An optical fiber delivery system terminated in spot-size specific handpiece.

b) An electronic power supply and interface circuitry.

c) An optical chamber containing laser rod and laser cavity optics.

No accessories are available for use with the accessory Nd:YAG sub-system.

Summary of Substantial Equivalence

Fotona believes that its Skinlight Plus Nd:YAG system is substantially equivalent to the Laserscope Aura system, previously cleared under K 951034.

The Fotona Skinlight Plus Nd:YAG system is intended for the photocoagulation of benign vascular and pigmented lesions. It therefore has the same Intended Use as the Laserscope Aura system.

Both of these lasers have a wavlength of 532nm. This wavelength is highly absorbed in soft tissue containing blood or melanin. Both lasers are therefore absorbed in an equally small volume of tissue, allowing for very precise action on the target tissue components.

Both lasers have a maximum average power capability of 10 Watts.

In terms of pulsewidth, both systems generate an envelope containing a series of individual pulses. In each case, an envelope width of 0.1 - 1.0 seconds may be preset. The envelope may also be extended to a continuous emission.

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 20856

Fotona
•c/o Iain D. Miller, Ph.D.
President
Medical Laser Solutions
304 Newbury Street, #339
Boston, Massachusetts 02115

SEP 2 3 1997

Re: K972368
Trade Name: Fotona Skinlight Plus Nd:YAG System
Regulatory Class: II
Product Code: GEX
Dated: June 23, 1997
Received: June 25, 1997

Dear Dr. Miller:

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 requirements , 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,

for 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

510(k) Number (if known): K972368

Device Name: Fotona Skinlight Plus Nd:YAG system

Indications For Use:

The Fotona Skinlight Plus Nd:YAG system is indicated for the photocoagulation of benign vascular and pigmented lesions.

(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 K972368

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)