K991634

AUG 10 1999

Appendix E : Summary of Safety and Effectiveness Data

General Information and Description

The Fotona Novalis R system is based on Ruby laser technology. Within the system, an optical cavity contains the Ruby crystal, which is activated by means of the use of flashlamps. Pulsed laser energy is provided through an optical fiber beam delivery system. While observing and directing the aiming beam (diode laser, 635 nm), the treatment beam is administrated by the physician through a footwitch. The laser is used in non-contact mode.

The System is capable of emitting up to 25 J of pulsed light at 694 nm. This light has a pulsewidth which varies in the range from 1 to 4 ms and can be adjusted by the user. The spot sizes from 8 to 14 mm can be chosen on the handpiece and are detected by the microprocessor controller. The corresponding energy fluence to tissue is displayed on a screen. The maximum fluence of 50J/cm^2 can be achieved by selecting the highest out energy and the smallest spot size.
The laser is intended to be used for removal of unwanted body hair.

The Novalis R 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 ruby laser rod, capable of generating 25 J optical pulses at a frequency up to 2 Hz.

d) An optical delivery system, interfacing the energy from the laser to the patient via an optical fiber and a 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 Novalis R :

- Fotona Novalis Er:YAG Laser
- CSC Device (Controlled Selective Cooling Device) or Cooling Gel or Cold Packs

Summary of Substantial Equivalence

Fotona believes that its Novalis R system is substantially equivalent to the Palomar EpiLaser Normal Mode Ruby Laser, Sharplan EpiTouch Ruby Laser and to the other previously FDA cleared Ruby lasers.

The predicate devices are cleared for removal of unwanted body hair. They therefore have the same Intended Use as the Fotona Novalis R.

Technologically, the predicate devices have identical characteristics to the Novalis R, all these devices comprising a flashlamp pumped ruby laser rod generating light at a wavelength of 694 nm, which is subsequently delivered to the patient via the fiber-optic delivery and handpiece.

The predicate devices have the ability to deliver laser energy at 694 nm, maximum fluence to tissue of 40J/cm^2 and are used with different skin cooling techniques. These characteristics are very similar to the Fotona Novalis R Ruby Laser System.

The risk and benefits for the Fotona Novalis R are comparable to the risk and benefits of the predicate devices when used for the same application.

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

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:

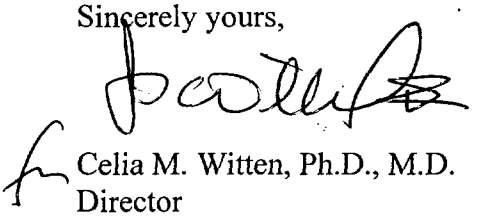
We have reviewed your Section 510(k) notification of intent to market the devices referenced above, and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date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

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,



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

APPENDIX F

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K991634

Device Name: **FOTONA NOVALIS R RUBY LASER SYSTEM**

Indications For Use:

The Fotona Novalis R Ruby Laser System for removal of unwanted body hair.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991634