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Appendix F : Summary of Safety and Effectiveness Data

K962902

General Information and Description

The Fotona Skinlight 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 Joule of pulsed light at 2.94 μm, with a (nominal) pulsewidth of 300 μs. The laser is intended to be used for cutting, vaporizing, and coagulating soft tissue.

The Skinlight 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 Joule 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.

Summary of Substantial Equivalence

Fotona believes that its Skinlight system is substantially equivalent to the Schwartz Electro-Optics (SEO) TriLase 2940 (K 953585).

The TriLase 2940 is cleared for the cutting, vaporization, and coagulation of soft tissue. It therefore has the same Intended Use as the Fotona Skinlight.

Technologically, the predicate has identical characteristics to Skinlight, both 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.

Both devices have identical energy delivery capabilities and similar repetition rates.

It is therefore believed that there are no new questions of Safety or Effectiveness raised by the introduction of this device.

Appendix G : Reference Literature

1. Anderson, RR "Selective Photothermolysis: precise microsurgery by selective absorption of pulsed radiation", Science 220, p 524-527.

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