

K072159

**510(K) Summary**

DEC 27 2007

Submitter: El.En. S.p.A.  
via Baldanzese, 17  
50041 Calenzano (FI), Italy

Contact: Andrea Tozzi  
Quality System Manager & Official Correspondent

Date Summary Prepared: July, 30, 2007

Device Trade Name: Smart CO<sub>2</sub> (SmartXide, Smart US20D) with DOT scanner

Common Name: Medical Laser System

Classification Name: Instrument, surgical, powered, laser  
79-GEX  
21 CFR 878.4810

Equivalent Device: Lumenis UltraPulse Encore and delivery device accessories

Device Description: The Smart CO<sub>2</sub> lasers (SmartXide, Smart US20D) are CO<sub>2</sub> laser, having a sealed CO<sub>2</sub> gas tube as the lasing medium. These are lasers with a wavelength of 10.6 μm. Laser activation is by a footswitch. Overall weight of the laser is 30 kg, and the size is 120 cm x 48 cm x 55 cm (H x W x D). Electrical requirement is 115VAC, 15A, 50-60 Hz, single phase.

Intended Use: The Smart CO<sub>2</sub> Lasers are indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues. The use with the scanning unit is indicated for ablative skin resurfacing.

Comparison: The Smart CO<sub>2</sub> Lasers are substantially equivalent to the Lumenis UltraPulse Encore lasers and delivery device accessories . They are both CO<sub>2</sub> lasers with a scanning unit as an accessory, for the identical indications for use.

Nonclinical Performance Data: None

Clinical Performance Data: None

Conclusion: The Smart CO<sub>2</sub> (SmartXide and Smart US20D) Lasers with DOT scanner are two more safe and effective devices for incision, excision, ablation, vaporization and coagulation of body soft tissue, including intraoral tissue.

Additional Information: None



DEC 27 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

El. En. Electronic Engineering S.p.A  
% Ms. Andrea Tozzi  
Quality System Manager  
Via Baldanzese, 17  
50041 Calenzano (FI), Italy

Re: K072159

Trade/Device Name: Smart CO<sub>2</sub> (SmartXide, Smart US20D) Laser with DOT scanner  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and plastic surgery  
and in dermatology  
Regulatory Class: Class II  
Product Code: GEX  
Dated: November 08, 2007  
Received: November 13, 2007

Dear Ms. Tozzi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(K) Number (if known): K072159

Device Name: Smart CO<sub>2</sub> (SmartXide, Smart US20D) Laser with DOT scanner

Indications For Use:

The smart CO<sub>2</sub> (SmartXide and Smart US20D) Lasers with DOT scanner are indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otolaryngology (ENT), gynaecology, neurosurgery, dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

Prescriptive Use X  
(Part 21 CFR 801 Subpart D)

OR

Over-the-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart C)

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchwald

(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

**510(k) Number** K072159