OCT 7 - 2004

Premarket Notification [510(k)] Summary
(per 21 CFR 807.92)

K042439

1. Submitted by:

Diamond Age Systems, Inc.
3775 South Laurel Way
Chandler, AZ 85249
Phone: (866) 546-5444

Contact Person: Geoffrey D. Swank
Vice-President of Laser Operations
Phone: (303) 263-3307
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Date Prepared: 29 August 2004

2. Device Name

Trade/Proprietary Name:	Azuryt Model CTL 1401, CO_2 Surgical Laser System
Common/Usual Name:	General Surgical Laser System
Classification Name:	Laser Instrument, Surgical, Powered (per 21 CFR 878.4810)

3. Predicate Device:

The Azuryt Model CTL 1401, CO_2 Surgical Laser System is substantially equivalent to other laser systems on the market, such as the Deka Smart CO_2 laser, cleared under K031224 and K031440; and the Lumenis LX-20 CO_2 Surgical Laser System, cleared under K896478, K953074, and K960475.

4. Intended use of the device

The Azuryt Model CTL 1401, CO_2 Surgical Laser System is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues, including intraoral tissues. These systems can be used in a variety of medical specialties, including general and plastic surgery, dentistry, oral/maxillofacial surgery, dermatology, gastroenterology, gynecology, otorhinolaryngology, aesthetical surgery, neurosurgery, oculoplastic, orthopedic, pulmonary/thoracic surgery, and urology.

5. Description of the Device

The, Azuryt Model CTL 1401 CO_2 Surgical Laser System is a CO_2 laser consisting of a power supply, cooling system, laser head, articulated arm, handpiece, microcomputer and control panel.

6. Summary of the technological characteristics of the device compared to the predicate device.

Like the predicate devices, the Azuryt Model CTL 1401 is a CO_2 surgical laser system, utilizing a laser with a wavelength of 10.6 µm. Each of these devices contains a power supply, a cooling system, a sealed CO_2 laser head delivering a beam with a wavelength of 10.6 µm, an arm to deliver the laser beam, a handpiece and a variety of accessories to address specific surgical needs.

7. Testing

The manufacturer of the Azuryt Model CTL 1401certifies that its device complies with the following international standards:

EN60825-1, IEC 60825-1, Safety of laser products – Part 1: Equipment classification, requirements and user's guide.

EN60601-2-22, IEC 60601-2-22, Medical Electrical Equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.

EN60601-1, IEC 60601-1, Medical Electrical Equipment – Part 1: General requirements for safety, as amended by amendment 1 (1991) and amendment 2 (1995).

EN60601-1-2, IEC 60601-1-2, Medical Electrical Equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests

The device also complies with the European Medical Device Directive 92/42/EEC and the US Federal Performance Standards 21 CFR 1040.10 and 21 CFR 1040.11 for Class IV Laser Products, except for deviations pursuant to Laser Notice No. 50, dated 26 July 2001.

8. Conclusions

Based upon the testing and comparison to the predicate devices, the Azuryt Model CTL 1401 has the same intended uses, with similar technological characteristics as the predicate devices. The system performs as intended and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Diamond Age Systems, Inc.
c/o Mr. Ned E. Devine
Entela, Inc.
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K042439
Trade/Device Name: Azuryt Model CTL 1401, CO_2 Surgical Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 21, 2004
Received: September 22, 2004

Dear Mr. Devine:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042439

Device Name: Azuryt Model CTL 1401, CO_2 Surgical Laser System

Indications For Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042439