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510(k) Summary Statement for the
Lumenis Family of Disposable Contact Tip Delivery Devices for CO_2 Lasers

I. General Information

Submitter:	Lumenis, Inc. 2400 Condensa Street Santa Clara, CA 95051
Contact Person:	Martha Murari, Ph.D. Senior Regulatory Affairs Associate Anne Worden Regulatory Consultant
Summary Preparation Date:	June 26, 2003

II. Names

Device Names:	Lumenis Family of Disposable Contact Tip Delivery Devices for CO_2 Lasers
Primary Classification Name:	Laser Powered Surgical Instruments (and Accessories)

III. Predicate Devices

- Lumenis Oral/ENT Fiber Delivery Devices (used with the UltraPulse Series CO_2 Surgical Lasers, K022060 and K974789);
- ESC Sharplan Series 2900 Synthetic Contact Tips (K894211);
- Surgical Laser Technologies (SLT) Contact and Diffuser Tips with Wavelength Conversion Surface Treatment (K010041, K980156, K882212, K872254, and K872253);
- Somnus Medical Technologies Somnoplasty System (K973618);
- ArthroCare Corporation Bipolar Electrosurgical ENTec Plasma Wands (K021364).

IV. Product Description

Lumenis Family of Disposable Contact Tip Delivery Devices for CO_2 Lasers is comprised of the following main components:

- Laser waveguide
- Specially-shaped tip
- Coupler connector

V. Indications for Use

The Lumenis Family of Disposable Contact Tip Delivery Devices for CO_2 Lasers is indicated for use in surgical applications requiring ablation, vaporization, excision, incision, and coagulation of soft tissue using laser-generated thermal energy in medical specialties, including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery, for the indications for use that the compatible laser system to which attached has been cleared.

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VI. Rationale for Substantial Equivalence

The Lumenis Family of Disposable Contact Tip Delivery Devices for CO_2 Lasers shares the same or similar indications for use in surgical applications, overall dimensions, tip shapes, tip/tissue temperature, materials, sterilization process, and system compatibility, and therefore is substantially equivalent to the Oral/ENT Fiber Delivery Devices manufactured by Lumenis (K022060), the predicate Series 2900 Synthetic Contact Tips manufactured by ESC Sharplan (K894211), the SLT Contact and Diffuser Tips with Wavelength Conversion surface treatment manufactured by Surgical Laser Technologies (K010041, K980156, K882212, K872254, and K872253), the Somnoplasty System manufactured by Somnus Medical Technologies (K973618), and the Bipolar Electrosurgical ENTec Plasma Wands manufactured by ArthroCare Corporation (K021364). In addition, validation data demonstrated adequate device performance.

VII. Safety and Effectiveness Information

Performance data were provided to demonstrate that the Lumenis Family of Disposable Contact Tip Delivery Devices for CO_2 Lasers operates in accordance with product specifications.

VIII. Conclusion

The Lumenis Family of Disposable Contact Tip Delivery Devices for CO_2 Lasers was found to be substantially equivalent to the predicate Lumenis Oral/ENT Fiber Delivery Devices (K022060), the predicate ESC Sharplan Series 2900 Synthetic Contact Tips (K894211), the SLT Contact and Diffuser Tips with Wavelength Conversion surface treatment (K010041, K980156, K882212, K872254, and K872253), the Somnus Medical Technologies Somnoplasty System (K973618), and the ArthroCare ENTec Plasma Wands (K021364). The Lumenis Family of Disposable Contact Tip Delivery Devices for CO_2 Lasers shares similar indications for use in surgical applications, design features, and similar functional features, and thus, is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 1 2003

Martha Murari, Ph.D.
Senior Regulatory Affairs Associate
Lumenis, Inc.
2400 Condensa Street
SWanta Clara, California 95051

Re: K030033
Trade/Device Name: Lumenis Family of Disposable Contact Tip Delivery Devices for CO_2 Lasers
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: June 26, 2003
Received: June 27, 2003

Dear Dr. Murari:

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 (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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 Miriam C. Provost

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 Statement as Requested by FDA

510(k) Number (if Known): K030033

Device Name: Lumenis Family of Disposable Contact Tip Delivery Devices for CO_2 Lasers

Indications For Use:

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Miriam C. Provost

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

510(k) Number K030033

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)