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Appendix A. **510(k) Summary**

This 510(k) Summary of Safety and Effectiveness for the Spectra Hair Removal Laser is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and follows the HHS Publication FDA 95-4158 concerning the content and organization of a 510(k) summary.

Applicant	SpectraGenics, Inc.,
Address:	7083 Commerce Circle, Ste. I Pleasanton, CA 94588
Contact person:	Robert E. Grove, Ph.D.
Telephone:	(925) 847-1762
Preparation date:	September 10, 2003
Device Trade Name:	Spectra Hair Removal Laser
Common Name:	Pulsed diode laser
Classification Name:	Laser Instrument, Surgical, Powered (Laser surgical instrument for use in general and plastic surgery and dermatology) Regulation No. 878.4810 Product Code: GEX; Panel: 79
Legally Marketed Predicate Devices:	LightSheer (StarLight) pulsed diode laser Star Medical / Coherent Star K973324, K982940, K001746 SLP 1000 (LC 100) pulsed diode laser Palomar Medical Technologies K010580, K011747 Apex 800 pulsed diode laser IRIDEX Corporation K020849 F1 pulsed diode laser Opus Medical, Inc. K030235

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System Description:	The Spectra Hair Removal Laser is a semiconductor diode laser system that delivers infrared light at a wavelength of nominally 800 nm.
Intended Use of the Device:	The Spectra Hair Removal Laser is intended to effect temporary hair removal.
Performance Data:	None. The specifications and indications for use of the Spectra Hair Removal Laser are a subset of those claimed in one or more of the clearances for the above-listed predicate devices. Thus performance data were not required.
Conclusion:	The Spectra Hair Removal Laser is substantially equivalent to the legally-marketed claimed predicate devices for the purposes of this 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2003

Robert E. Grove, Ph.D.
President and CEO
SpectraGenics, Inc.
7083 Commerce Circle, Suite I
Pleasanton, California 94588

Re: K032846
Trade/Device Name: Spectra Hair Removal Laser
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 5, 2003
Received: September 15, 2003

Dear Dr. Grove:

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. 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,

Miriam C. Provost

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): K032846

Device Name: Spectra Hair Removal Laser

Indications for Use: Temporary hair removal

Prescription Use ✓ AND/OR Over the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTUNUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032846