K060567

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the SpectraGenics ATS-1 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:	5880 West Las Positas Blvd., Suite 52 Pleasanton, CA 94588-8522
Contact person:	Robert E. Grove, Ph.D.
Telephone:	(925) 398-2049
Preparation date:	March 1, 2006
Device Trade Name:	SpectraGenics ATS-1
Common Name:	Light Therapy Device
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:	ClearLight Phototherapy System, Model CL420 CureLight Ltd. K013623 iClear Phototherapy System, Model FCGM0002 K030338 Omnilux Blue Photo Therapeutics, Ltd. K030883 Palomar LuxV Handpiece Palomar Medical Technologies, Inc. K040081

	Palomar StarLux Pulsed Light System Palomar Medical Technologies, Inc. K041086 Radiancy Acne System with ClearTouch Light Unit Assembly K051268, K032205
System Description:	The SpectraGenics ATS-1 is a handheld, electrically-powered light therapy device that produces light at a wavelength of nominally 410 nm.
Intended Use of the Device:	The SpectraGenics ATS-1 is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
Performance Data:	The specifications and indications for use of the SpectraGenics ATS-1 are substantially equivalent to those claimed in one or more of the clearances for the above-listed predicate devices. Clinical data is provided to demonstrate the safety and efficacy of the SpectraGenics ATS-1.
Conclusion:	The SpectraGenics ATS-1 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

SpectraGenics, Inc.
c/o Robert E. Groves, Ph.D.
President & CEO
5880 West Las Positas Boulevard – Suite 52
Pleasanton, California 94588-8522

APR 2 8 2006

Re: K060567
Trade/Device Name: SpectraGenics ATS-1
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: March 1, 2006
Received: March 10, 2006

Dear Dr. Groves:

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.

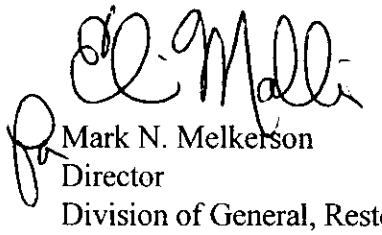
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



Mark N. Melkerson
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): K060567

Device Name: SpectraGenics ATS-1

Indications For Use:

The SpectraGenics ATS-1 is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

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-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K060567