

K973324

Attachment VI

DEC - 3 1997

510(K) Summary of Safety and Effectiveness

This 510(K) Summary of Safety and Effectiveness for the StarLight™ Pulsed Diode Array Laser System is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(K) summary.

Applicant: Star Medical Technologies, Inc.

Address: 1249 Quarry Lane, Suite 100
Pleasanton, CA 94566

Contact Person: Robert E. Grove, Ph.D.

Telephone: 510-484-2140

Preparation Date: August 26, 1997

Device Trade Name: StarLight™ Pulsed Diode Array Laser System

Common Name: Pulsed Diode Array Laser

Classification Name: Laser surgical instrument for use in General and Plastic Surgery and in Dermatology (see: 21 CFR 878-4810).
Product Code: GEX
Panel: 79

Legally-Marketed Predicate Device: EpiLaser™ Normal Mode Ruby Laser
Spectrum Medical Technologies, Inc.
K963947

System Description: The StarLight™ delivers pulsed infrared laser light with a wavelength of 800 nm, a selectable pulse duration of 5 – 30 ms, and a selectable pulse energy of 8 – 32 J. The corresponding fluence delivered through the 9 x 9 mm handpiece tip is 10 – 40 J/cm². The laser pulses are generated at a maximum pulse repetition frequency of 1 Hz by an array of diode lasers located in the handpiece.

The complete system consists of a console, a footswitch, and a handpiece connected to the console with an umbilical. In standard use, the handpiece is pressed against the patient's skin and a light pulse is delivered when the footswitch and handpiece trigger are depressed. The handpiece tip is water-cooled to provide active skin cooling. Laser parameters and other system features are controlled from the touch-screen on top of the console, which provides an interface to the system computer.

Intended Use of the Device:

The StarLight™ Pulsed Diode Array Laser System is indicated to remove hair in Dermatology and Plastic Surgery procedures.

Performance Data:

Clinical studies were conducted to provide assurance that differences in the specifications of the StarLight™ laser and the predicate device did not result in different performance or raise new questions of safety or efficacy.

Results of Clinical Study:

Observations of hair regrowth and skin responses were recorded prior to treatment and at 1, 3, 6, and 9 months after treatment. There was no scarring or permanent depigmentation of the skin in any subject. The study demonstrated that the StarLight™ Pulsed Diode Array Laser System is a safe and effective tool for hair removal, resulting in significant hair loss and prolonged growth delay.

Conclusion:

Based on the foregoing, the StarLight™ Pulsed Diode Array Laser System is substantially equivalent to the legally-marketed claimed predicate device, i.e., the Spectrum EpiLaser™ for hair removal.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 1997

Star Medical Technologies, Incorporated
C/O Ms. Marcy Moore
Manager of Clinical Studies
Palomar Medical Technologies, Incorporated
9516 Candor Oaks Drive
Raleigh, North Carolina 27615

Re: K973324
Trade Name: StarLight™ Pulse Diode Array Laser System
Regulatory Class: II
Product Code: GEX
Dated: August 28, 1997
Received: September 4, 1997

Dear Ms. Moore:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

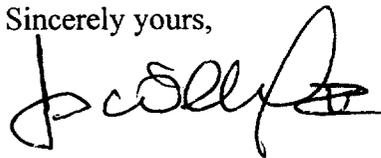
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for

devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten

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

Enclosure

K973324

INDICATION FOR USE STATEMENT

510(K) Number: Pending

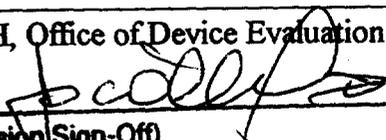
Device Name: StarLight™ Pulsed Diode Array Laser System

Indications for Use:

The StarLight™ Pulsed Diode Array Laser System is intended to remove hair in Dermatology and Plastic Surgery procedures.

(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 Devices
510(k) Number K973324

Prescription Use

OR Over-the-Counter Use _____
(per 21 CFR 801.109)