

K974346

JAN 16 1998

**Attachment 9**

**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:** November 14, 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:** PhotoGenica LPIR™  
Cynosure, Inc.

**System Description:** The StarLight system delivers pulsed infrared laser light with a wavelength of 800 nm, a selectable pulse duration of 5 – 30 ms, and a selectable fluence of 10 – 40 J/cm<sup>2</sup>. The corresponding pulse energy delivered through the 9 x 9 mm handpiece tip is 8 – 32 J. 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 intended for the treatment of leg veins in Dermatology and Plastic Surgery procedures.

**Performance Data:** Clinical studies were conducted to provide assurance that differences in the specifications of the StarLight system and the predicate device do not result in different performance or raise new questions of safety or efficacy.

**Results of Clinical Study:** Observations of vessel clearing and skin responses were recorded as a function of vessel and treatment parameters. Vessel effects included reduction in vessel diameter, vessel coagulation, and vessel disappearance. 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 the treatment of leg veins.

**Conclusion:** Based on the foregoing, the StarLight Pulsed Diode Array Laser System is substantially equivalent to the legally-marketed claimed predicate device for the purposes of this 510(K) submission.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 16 1998

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

Re: K974346  
Trade Name: StarLight™ Pulsed Diode Array Laser System  
Regulatory Class: II  
Product Code: GEX  
Dated: November 14, 1997  
Received: November 19, 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.

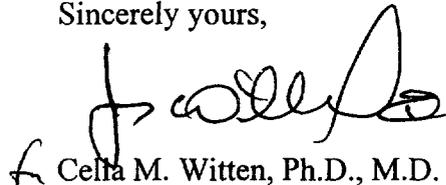
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,



Cella M. Witten, Ph.D., M.D.

Director

Division of General and

Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K974346

**INDICATION FOR USE STATEMENT**

510(K) Number: Pending

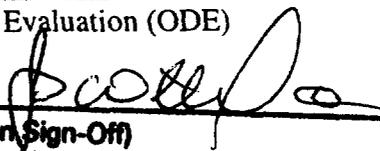
Device Name: StarLight™ Pulsed Diode Array Laser System

**Indications for Use:**

The StarLight™ Pulsed Diode Array Laser System is intended for the treatment of leg veins 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 K974346

Prescription Use

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