4/8/99

K992940

Attachment 4

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the LightSheer™ Pulsed Diode Array Laser 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. Robert E. Grove, Ph.D., President
Address:	1249 Quarry Lane Pleasanton, CA
Contact Person:	Marcy Moore Manager of Clinical Studies
Telephone:	919-676-7166
Fax:	919-676-3683
Preparation Date:	August 17, 1998
Device Trade Name:	LightSheer™ Pulsed Diode Array Laser
Common Name:	LightSheer™ Diode Laser System
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:	LightSheer™ Pulsed Diode Array Laser Star Medical Technologies, Inc. k973324
System Description:	The LightSheer™ 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/cm^2. 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 handpiece tip is water-cooled to provide active skin cooling.
Intended Use of the Device:	The LightSheer™ is intended to effect temporary hair reduction. The LightSheer® is also intended to effect stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regime.
Performance Data:	There are no technological differences.
Results of Clinical Study:	Observations of hair and skin responses were recorded prior to treatment and at 1, 3, 6, 9, and 12 months after treatment. There was no scarring or permanent skin injury in any subject. The study demonstrated that LightSheer™ is a safe and effective tool for permanent hair reduction.
Conclusion:	Based on the foregoing, the LightSheer™ is effective for producing a long-term stable, permanent reduction of hair.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 8 1999

Star Medical Technologies, Inc
c/o Ms. Marcy Moore
Manager of Clinical Studies
9516 Candor Oaks Drive
Raleigh, North Carolina 27615

Re: K982940
Trade Name: LightSheer™ Pulsed Diode Array Laser System
Regulatory Class: II
Product Code: GEX
Dated: February 1, 1999
Received: February 3, 1999

Dear Ms. Moore:

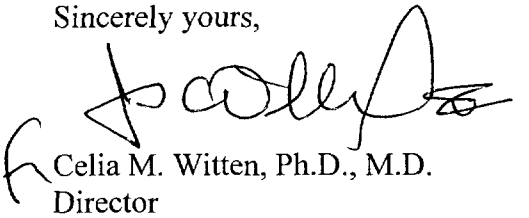
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K982940

Device Name: LightSheer™ Pulsed Diode Array Laser

Indications for Use:

The LightSheer™ is intended to effect temporary hair reduction. The LightSheer™ is also intended to effect stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regime.

(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 K982940
510(k) Number

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