K020973

MAR 2 9 2002

510(k) Summary of Safety and Effectiveness
The SurgiLight, Inc. EX-308

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the SurgiLight, Inc. EX-308 is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices which include the following: PhotoMedix

I. **Company:** SurgiLight, Inc.
12001 Science Drive
Orlando, Florida 32826
J. T Lin, Ph.D.

II. **Model:** SurgiLight, Inc. EX-308 Excimer Laser

III. **Predicate Devices:** The PhotoMedix K003705

IV. **Description:** The SurgiLight EX-308 Excimer Laser is a medical device that is capable of emitting a treatment laser beam at a wavelength of 308nm under the guidance of a visible aiming beam. This laser may be used in a pulsed mode at various repetition rates.

V. **Indications For Use:** The SurgiLight, Inc. EX-308 Excimer laser, handpieces and laser related accessories is currently cleared for the treatment of psoriasis and will be indicated for use for the treatment of vitiligo. These indications have been cleared for marketing by the Food and Drug Administration for the cited predicated devices. SurgiLight, Inc. seeks no new indications for the EX-308 Excimer Laser. No new indications were sought in this premarket notification, clinical data was presented.

Summary: From a design and clinical perspective, the predicate and candidate laser devices, are of similar technology and have the same intended use. Based upon an analysis of the overall performance characteristics for the devices, SurgiLight, Inc. believes that no significant differences exist. Therefore, the SurgiLight, Inc. EX-308 should not raise any concerns regarding its overall safety and/or effectiveness.

Advisory: This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients due to operator error or in procedures requiring a high degree of skill.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2002

J. T. Lin, Ph.D.
Director of Business and
New Technology Development
SurgiLight, Inc.
12001 Science Drive, Ste. 140
Orlando, FL 32826

Re: K020973
Trade/Device Name: SurgiLight, Inc. EX-308 Excimer Laser
Regulation Number: 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 27, 2001
Received: March 26, 2002

Dear Dr. Lin:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Miriam C. Provost

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): K020973

Device Name: SurgiLight, Inc. EX-308 Excimer Laser

Indications for Use:

The SurgiLight, Inc. EX-308 Excimer laser, handpieces and laser related accessories is indicated for use for the treatment of psoriasis and for the treatment of vitiligo.

Miriam C. Provost

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

510(k) Number K020973

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use _____

(Optional Format 1-2-96)