

JUL 1 8 2000

K 993328

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: Phototherapeutix, Inc. 2480AB and the National Biological Corporation Houva II

- 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 Phototherapeutix, Inc. 2480AB (K935525) and the National Biological Corporation Houva II (K885029).
- 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 will be indicated for use for the treatment of psoriasis. 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.



JUL 1 8 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Timothy J. Shea
Executive Vice President and
Chief Operating Officer
SurgiLight, Inc.
12001 Science Drive, Suite 140
Orlando, Florida 32826

Re: K993328
Trade Name: EX-308 Excimer Laser
Regulatory Class: II
Product Code: GEX
Dated: May 9, 2000
Received: May 9, 2000

Dear Mr. Shea:

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.

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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,

DMC R. Voelker

SM 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

Page _____ of _____

510(k) Number (If known): K993328

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

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dan R. Kochner

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K993328

Prescription Use ✓

Or

Over-The-Counter Use _____

(Optional Format 1-2-96)