APR 2 9 2005

K050950

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Device Name: Various models of the Crystal family photoepilation system.
Trade / Proprietary Device Name: Crystal-512
Record-618
Optima-518

Establishment Name and Registration Number of Submitter

Name: Active Optical Systems Ltd.
Registration Number: In process
Contact person: Efraim Bidas or Gil Bidas
Address: 24 Herzel st. Petach Tikva, Israel
Tel: ++97239341682 **Fax:** ++97239302888

Device Classification

Product Code:	GEX
Regulation Number:	878.4810
Common Name:	Pulsed light hair removal system
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology. (21 CFR 878.4810)
Regulatory class:	Class II

Reason for 510(k) Submission

Traditional 510(k) Submission

Identification of Legally Marketed Equivalent Devices

SkinStation K030897, **StarLux** K033549

Device Description

The Crystal & Record are two models of the same device. The Optima is an additional commercial name of the Record. The device applies photothermal energy to human skin tissue to effect a desired change in the structure of the tissue. The energy is transmitted from a light source to the target tissue by a Treatment Handpiece that is in contact with the skin.

Indications for use

The Crystal, Record & Optima are generally intended for dermatological use. The device is specifically indicated for removal of hair by using selective light energy.

Safety & Effectiveness

The device has been designed verified and validated complying to 21CFR 820.30 regulations. Bench and clinical data demonstrate that the Crystal, Record & Optima meet the required specifications. No adverse affects have been detected.

Substantial Equivalency

It is Active Optical Systems' opinion that the Crystal, Record & Optima are substantially equivalent in terms of safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2005

Active Optical Systems, Ltd.
C/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K050950
Trade/Device Name: Crystal, Record & Optima
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: April 12, 2005
Received: April 15, 2005

Dear Mr. Job:

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), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Form

510(k) Number (if known): K050950

DEVICE NAME: Crystal , Record & Optima

INDICATION FOR USE:
The Crystal , Record & Optima are generally intended for dermatological use. The device is specifically indicated for removal of hair by using selective light energy.

(Please do not write below this line - continue on another page if needed)

(Concurrence of CDRH, Office of Device Evaluation (ODE))

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

510(k) Number K050950

Prescription Use X OR Over-the-Counter Use ~~Over-the-Counter Use~~
(Per 21 CFR 801.109)