510(k) SUMMARY
PhotoMedex, Inc.
XTRAC XL Plus Excimer Laser System, model AL7000

1. GENERAL

- *Submitter:* PhotoMedex, Inc.
  2431 Impala Drive
  Carlsbad, CA 92008

- *Contact Person:* Bob Rose
- *Date Prepared:* May 5, 2003

2. DEVICE NAME

- *Classification name:* (21 CFR §878.4810; Laser Surgical Instrument for use in General and Plastic Surgery and Dermatology

- *Common or usual name:* XeCl excimer laser

- *Trade or proprietary name:* XTRAC XL Plus Excimer Laser System, model AL7000

3. PREDICATE DEVICES

Excimer Laser

- XTRAC Excimer Laser System, model AL7000
  Photomedex, Inc.
  510(k) numbers: K992914, K003705, K011382 & K020847

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4. DEVICE DESCRIPTION

The XTRAC XL Plus Excimer Laser Phototherapy System is a complete self-contained compact UV laser light source, which utilizes a XeCl gas mixture to generate dose-selected and target specific ultraviolet light at wavelength of 308 nm. The laser system consists of a keypad and display, a fiberoptic delivery system, a handpiece and a foot-switch. The laser is enclosed in a protective interlocked housing.

5. INTENDED USE

The intended use is UVB phototherapy of targeted skin for treatment psoriasis, vitiligo, atopic dermatitis and leukoderma.

6. SUBSTANTIAL EQUIVALENCE

Current published data supports 308 nm UVB to be effective of providing efficacy to the currently approved indications for use, which the AL7000 has been previously cleared for.

The intended use for the PhotoMedex XTRAC XL Plus Excimer Laser System is within the scope of the predicate device, the current market cleared PhotoMedex AL7000 excimer laser phototherapy system. Both device types share the same methods and mechanisms to produce targeted and controlled doses of UV light to affected target areas.

The XTRAC Excimer Laser System, model AL7000 is market cleared per 510(k) numbers K992914, K003705, K011382, & K020847 for the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma.

7. PRODUCT PERFORMANCE TESTING

Testing conducted on the XTRAC XL Plus Excimer Laser Phototherapy System includes conformance to all relevant international EN 60601 series of standards and applicable laser Performance Standards (21 CFR Part 1040.10 & 1040.11), as well as UL 2601.

8. CONCLUSIONS

Based on the intended use, the previously cleared technological characteristics of the AL7000, and the performance data documented to support the modifications, PhotoMedex believes that the XTRAC XL Plus Excimer Laser Phototherapy System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2003

Mr. Bob Rose
Director of RA/QA
PhotoMedex, Inc.
2431 Impala Drive
Carlsbad, California 92008

Re: K031451
Trade/Device Name: XTRAC XL Plus Excimer Laser System, Model AL7000
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: May 5, 2003
Received: May 15, 2003

Dear Mr Rose:

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 (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) you may obtain. 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,

Miriam C. Provost

for 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

510(k) Number (if known): K031451

Device Name: *XTRAC XL Plus Excimer Laser System, model AL7000*

Indications for Use:

UVB Phototherapy for psoriasis, vitiligo, atopic dermatitis, and leukoderma

(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 _____
(Per 21 CFR 801.109)

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

510(k) Number K031451