OCT 1 4 2004

K041943

510(k) SUMMARY
PhotoMedex, Inc.
XTRAC XL² Excimer Laser System, Model AL8000

1. GENERAL

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

- *Contact Person:* Bob Rose
- *Date Prepared:* July 16, 2004

2. DEVICE NAME

- *Classification name:* Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR §878.4810)

- *Common or usual name:* XeCl excimer laser

- *Trade or proprietary name:* XTRAC XL² Excimer Laser System, Model AL8000

3. PREDICATE DEVICES

Excimer Laser

- Excimer Laser Phototherapy System, model AL7000, AccuLase (PhotoMedex), cleared via 510(k) K992914

- XTRAC Excimer Laser System. Model AL7000, PhotoMedex, Inc., cleared via 510(k) K003705

- XTRAC Excimer Laser System. Model AL7000, PhotoMedex, Inc., cleared via 510(k) K011382

- XTRAC Excimer Laser System. Model AL7000, PhotoMedex, Inc., cleared via 510(k) K020847

- XTRAC XL Plus Excimer Laser System. Model AL7000, PhotoMedex, Inc. cleared via 510(k) K031451

4. DEVICE DESCRIPTION

The XTRAC XL² Excimer Laser System Model AL8000 is a complete self-contained compact UVB laser light source, which utilizes a XeCl gas mixture to generate an operator selected dose and target-specific ultraviolet light at monochromatic wavelength of 308 nm. The laser system consists of a touch-screen display, an advanced fiberoptic cable attached to a handpiece, and a foot-switch to initiate exposure. The laser is enclosed in a protective interlocked housing. The unit is designed to operate on standard AC power available from wall outlets and can accommodate US, European and other nominal supply voltages and operating frequencies.

5. INTENDED USE

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

6. SUBSTANTIAL EQUIVALENCE

The application of the Excimer Laser phototherapy has been proven to be substantially equivalent to current legally marketed devices in the treatment of indications previously cleared by CDRH (ODE). PhotoMedex has been granted clearance via K992914, K003705, K011382, K020847, and K031451 for this method of phototherapy generation.

The intended use for the PhotoMedex XTRAC XL² Excimer Laser System, Model AL8000, and the identified predicate devices are identical in that they are all excimer lasers used to produce monochromatic (308nm) UVB light for the purpose of targeted, dose controlled UVB (dermatological) phototherapy. The differences between the XTRAC XL² Excimer Laser System Model AL8000, and the identified predicates are limited to a reduction in product size and weight, improved ergonomics for the user, enhanced operating parameters, and additional minor internal improvements to reduce (required) maintenance costs. We believe the inclusion of these features does not affect the device's safety or intended use as compared to the identified predicates.

7. CLINICAL PERFORMANCE TESTING

All clinical indications requested in this application have been previously cleared in the identified predicate devices. The XTRAC XL² Excimer Laser System Model AL8000 does not introduce any new indications for use, and will perform in an identical manner as the identified predicates, therefore PhotoMedex believes duplicative clinical data is not required as a condition of granting market clearance for the XTRAC XL² Excimer Laser System Model AL8000.

8. PRODUCT PERFORMANCE TESTING

Testing and certification relevant to the XTRAC XL² Excimer Laser System Model AL8000 includes conformance to current applicable international EN 60601 series of standards, 21 CFR Part 1040.10 & 1040.11 *Performance Standards for Light-Emitting Products* and also includes UL 2601-1/UL60601-1 Medical Electrical Equipment classified device. Products are produced and distributed within a facility that has been registered by FDA to manufacture medical devices. The XTRAC XL² Excimer Laser System Model AL8000 also is reviewed for risk management utilizing EN ISO 1497, *Application of risk management to medical devices* ensuring all aspects of the device are reviewed for potential hazards.

9. CONCLUSIONS

PhotoMedex believes the XTRAC XL² Excimer Laser System Model AL8000 is substantially equivalent to the identified predicates in that it does not introduce any new issues of safety or efficiency as compared to the predicates. The Indications for use, methods of operation and power source is identical to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 4 2004

Mr. Bob Rose
Director of Regulatory Affairs
and Quality Assurance
PhotoMedex, Inc.
2431 Impala Drive
Carlsbad, California 92008

Re: K041943
Trade/Device Name: XTRAC XL^2 Excimer Laser System Model AL8000
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: July 16, 2004
Received: July 19, 2004

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.

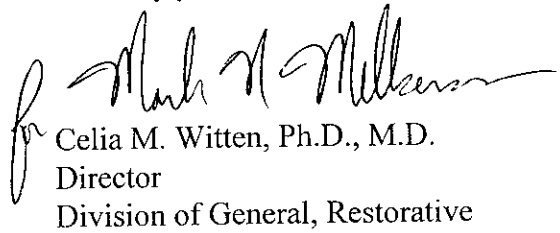
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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/dsma/dsmamain.html

Sincerely yours,



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): K041943

Device Name: ***XTRAC XL² Excimer Laser System Model AL8000***

Indications For Use:

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

for Mark N Milkerson

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

510(k) Number K041943

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)