JAN 27 2000

K 992914

510(k) SUMMARY
AccuLase, Inc.
Excimer Laser Phototherapy System, AL7000

1. GENERAL

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

- *Contact Person:* Al Memmolo
- *Date Prepared:* January 14, 1999

2. DEVICE NAME

- *Classification name:* Ultraviolet lamp for dermatological disorders (per 21 CFR §878.4630)

- *Common or usual name:* XeCl excimer laser

- *Trade or proprietary name:* Excimer Laser Phototherapy System, AL7000

3. PREDICATE DEVICES

Ultraviolet Lamps

- HOUVA II, Phototherapy System
  National Biological Corporation
  510(k) number: K885026
- UviSol, Phototherapy System
  National Biological Corporation,
  510(k) number K934808

Excimer Laser

- CVX-300 Excimer Laser System
  Spectranetics Corp.
  PMA number: P910001

510 (k) Summary
AL7000

4. DEVICE DESCRIPTION

The Excimer Laser Phototherapy System, AL7000 is a complete self-contained compact laser light source, which utilizes a XeCl gas mixture to generate ultraviolet light at wavelength of 308 nm wavelength. The laser system consists of a keypad and display, a fiberoptic delivery system, a footswitch, and a handpiece. The laser is enclosed in a protective interlocked housing.

5. INTENDED USE

UVB phototherapy for Psoriasis

6. SUBSTANTIAL EQUIVALENCE

The intended use for the **AccuLase Excimer Laser Phototherapy System, AL7000** is identical to that of the predicate ultraviolet lamps. Both device types share the same methods and mechanisms of treatment.

The Excimer Laser Phototherapy System is substantially equivalent to the technological characteristics of the predicate excimer laser device. Both devices share the same operating principles and produce an identical wavelength.

7. CLINICAL PERFORMANCE DATA

A dose response study using a 308 nm excimer laser showed the safety and effectiveness of the excimer laser for the treatment of Psoriasis.

8. PRODUCT PERFORMANCE TESTING

Testing conducted on the Excimer Laser Phototherapy System, AL7000 includes conformance to all relevant International EN 60601 / IEC 601 series of standards and applicable laser standards.

9. CONCLUSIONS

Based on the same intended use as ultraviolet lamps, the similar technological characteristics of the excimer lasers, and the clinical and performance data, AccuLase believes that the Excimer Laser Phototherapy System, AL7000 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2000

Mr. Al Memmolo
Director, Quality Assurance and
Regulatory Affairs
AccuLase, Inc.
2431 Impala Drive
Carlsbad, California 92008

Re: K992914
Trade Name: Excimer Laser Phototherapy System, AL7000
Regulatory Class: II
Product Code: GEX
Dated: November 24, 1999
Received: November 29, 1999

Dear Mr. Memmolo:

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.

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,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AccuLase, Inc.

(a subsidiary of Laser Photonics, Inc.)

510(k) Number (if known): K992914

Device Name: ***Excimer Laser Phototherapy, AL7000***

Indications For Use:

UVB Phototherapy for Psoriasis

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992914

Prescription Use X OR Over-The-Counter-Use ____
(Per 21 CFR 801.109)