

# AccuLase, Inc.

(a subsidiary of Laser Photonics, Inc.)

K992914

510(k) Number (if known): \_\_\_\_\_

Device Name: Excimer Laser Phototherapy, AL7000

Indications For Use:

*UVB Phototherapy for Psoriasis*

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PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K992914

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_

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

#### **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.