510 (k) PRE-MARKET NOTIFICATION SUMMARY K062963

General Information: This 510(k) provides notification of substantial equivalence for RA MEDICAL SYSTEMS, INC.'s PHAROS Excimer Laser, which is substantially equivalent to several previously marketed devices, including PhotoMedex's Xtrac AL7000 and AL8000, SurgiLight EX-308, and the Lumins BClear Photo Clearing System. It is intended for use in the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma.

Submitted by: RA MEDICAL SYSTEMS, INC.

Address: 2270-L Camino Vida Roble
Carlsbad, CA 92011

APR - 3 2007

Contact Person: Dean Irwin
President

Date Prepared: 27 September 2006

Device Trade Name: PHAROS Excimer Laser EX-308

Device Common Name: XeCl excimer laser, excimer phototherapy laser.

Classification: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR §878.4810). Product Code: GEX

Predicate Device: SurgiLight Inc.
EX-308 Excimer Laser, 510(k) numbers: K993328 and K020973.

PhotoMedex
XTRAC Excimer Laser, model AL7000, 510(k) numbers:
K992914, K003705, K020847, and K011382
XTRAC Excimer Laser, model AL8000, 510(k) number: K041943

Lumins Inc.
BClear Targeted PhotoClearing System, 510(k) numbers:
K011197, K020591 and K021762.

TheraLight, Inc.
Targeted UVA / UVB Phototherapy System, model UV120-2
UVA/UVB, 510(k) numbers: K024020 and K022165.

National Biological Corp.
Houva 3 With PhotoSense II, 510(k) numbers K041212

Device Description: RA Medical Systems, Inc.'s PHAROS Excimer Laser is a medical laser that is a self-contained UV laser light source that emits a wavelength of 308 nm. The PHAROS Excimer Laser utilizes a XeCl gas mixture to generate an operator-selected dose and target-specific UV light. The laser dose is activated by a footswitch with the therapeutic radiation emitting from a handheld device. The laser operation is key controlled and is contained within an interlocked housing.

Intended Use: UVB phototherapy for the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma.

Substantial Equivalence: The PHAROS Excimer Laser, from both a design and clinical perspective, uses similar or identical technology as the cited predicate devices and has the same intended uses. Based upon the predicted overall performance characteristics for the PHAROS Excimer Laser, RA Medical Systems, Inc. believes that no significant differences exists between PHAROS and the cited predicate devices.

Product Performance Testing: Testing conducted on the PHAROS EX-308 laser shows that it conforms to the relevant applicable standard.

Clinical Performance Testing: the indications requested have been previously cleared in predicate devices. The PHAROS EX-308 does not introduce any new indications for use, and will clinically perform equivalent to the predicate devices.

Conclusions: The PHAROS EX-308 Excimer laser uses a similar or identical technology as the predicate devices. Therefore, RA Medicals Systems, Inc.'s PHAROS Excimer laser should not raise any concerns regarding the safety and effectiveness of the laser to treat psoriasis, vitiligo, atopic dermatitis and leukoderma. Ra Medical believes that the PHAROS EX-308 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

RA Medical Systems, Inc.
% Mr. Dean Irwin
2270-L Camino Vida Roble
Carlsbad, California 92011

APR - 3 2007

Re: K062963
Trade/Device Name: PHAROS EX-308 Excimer Laser System
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: March 6, 2007
Received: March 13, 2007

Dear Mr. Irwin:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

FOR

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

OSPURY Director
4/4/07

Enclosure

Indications for Use

510(k) Number (if known): K062963

Device Name: PHAROS EX-308 Excimer Laser System

Indications for Use: The PHAROS Excimer Laser will be indicated for use for the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma.

Prescription use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K062963