JUL 27 2004

K041103 1 of 2

FDA 510 K Summary of Safety and Effectiveness for AcneLift

1. General Information

Submitter:	Inner Act, LLC 4750 Turbo Circle Reno, Nevada 89502 775-829-2566 Fax: 775-829-7588
Contact Person:	Ronnie Lamberton MD At above address, cell: 909-378-9536
Summary Preparation Date:	April 12, 2004

2. Names

Device Name:	AcneLift
Classification Name:	Laser instrument, surgical, powered device; GEX; Class II category.

3. Predicate Device

AcneLift is substantially equivalent to the Omnilux Blue (K030883)

4. Device Description

AcneLift uses panels of LED's which emit visible light of 407 $\pm$ 5 nm and is not associated with the risks or harmful side effects of ultraviolet radiation. Thermal Management is achieved by a fan mounted in close proximity to an aluminum heat sink. The lights are mounted to a mechanical arm and are controlled by an analog timing device. The treatment area is approximately 960 cm^2. The total light emitted is 42 Watts giving a fluence of about 45 mW/cm^2. Thus, AcneLift provides 50 Joules/cm of energy, in approximately 18-20 minutes.

5. Indications for Use

AcneLift™ is generally indicated for treatment of dermatological conditions and specifically indicated for the treatment of moderate inflammatory acne vulgaris.

6. Performance Data

Based on analysis of performance characteristics of Omnilux Blue and AcneLift, Inneract LLC does not believe that any significant differences exist. Therefore, the AcneLift device does not impose any new safety or effectiveness concerns.

"Software"

AcneLift™ does not use any software programs. The treatment time, is controlled by a digital timer which turns off the LED's after the selected time interval.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2004

Ronald W. Lamberton, M.D.
Medical Director of Research
and Development
Inner Act, LLC
4750 Turbo Circle
Reno, Nevada 89502

Re: K041103
Trade/Device Name: AcneLift
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: April 12, 2004
Received: May 20, 2004

Dear Dr. Lamberton:

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. 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,

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

Indications for Use

510(k) Number (if known): K041103

Device Name: AcneLift

Indications For Use:

AcneLift™ is generally indicated for the treatment of dermatological conditions and specifically indicated for the treatment of moderate inflammatory acne vulgaris.

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

Miriam C. Provost

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

510(k) Number K041103