# SECTION 5. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K072035

## 5. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

OCT 16 2007

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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| **APPLICANT** | Allux Medical Incorporated<br>1430 O'Brien Drive, Suite F<br>Menlo Park, California 94025<br><br>Contact Person: Lloyd H. Griese<br>Vice President, Quality Assurance<br>Telephone No: (650) 473-9407 x113<br>Fax No: (650) 473-9809<br>E-mail: lgriese@alluxmedical.com |
| **TRADE NAME:** | Resolve™ UVB Phototherapy System |
| **COMMON NAME:** | UV Phototherapy Device |
| **CLASSIFICATION NAME:** | Ultraviolet lamp for dermatologic disorders<br>(See 21 CFR 878.4630) |
| **DEVICE CLASSIFICATION:** | Class II |
| **PRODUCT CODE** | FTC |
| **PREDICATE DEVICES:** | Lumenis, Ltd. Bclear™ UVB Phototherapy System (K020591)<br>TheraLight, Inc. UV120-2 UVA / UVB Phototherapy System (K022165)<br>Natus Medical, Inc. Natus® Blue Light Phototherapy Unit (K022196)<br>Respironics Inc. Bili-Tx Neonatal Phototherapy Device (K070180) |

**Description of Device:**

The Resolve™ UVB Phototherapy System is designed to deliver therapeutic ultraviolet-B light to a localized area onto a patient's skin surface. This system is designed to be easy to operate and is intended to be used in an outpatient setting such as a dermatologist's office under supervision of trained medical personnel.

The device is comprised of two distinct components. The first is a patient attached unit and the second is a medical grade power supply. The patient attached unit is small and lightweight and is intended to be held in place or affixed to a patient at the desired treatment site. A portion of one side of the patient attached unit is composed of a fused silica transparent window out of which ultraviolet light is emitted; this window surface is intended to make contact with and lay flush to the skin thus enabling a localized treatment.

The patient attached unit houses an array of ultraviolet light emitting diodes (UV-LEDs) that serve as the therapeutic light source. Additionally, the drive and control circuitry necessary to operate the UV-LEDs, as well as a fan and heat sink to dissipate waste thermal energy, are located inside the patient attached unit's protective housing. Operator interface features include on-off switch and both visual and audible status indicators.

**Indications for Use:**

The Resolve™ UVB Phototherapy System is an ultraviolet light emitting medical device indicated for phototherapeutic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. The Allux Medical Resolve™ UVB Phototherapy System is intended to be used with all Skin Types (I – VI).

**Description of Substantial Equivalence:**

Currently published clinical data support UVB phototherapy treatment for a variety of dermatologic conditions. The intended use of the Resolve UVB Phototherapy System is considered by Allux Medical to be within the scope of the predicate devices that emit UVB light for dermatologic phototherapy. The Resolve UVB Phototherapy System employs light emitting diodes (LEDs) as a light source. This technological feature is not considered by Allux Medical to raise new questions of safety or efficacy. Use of LEDs as a therapeutic light source in medical devices is within the scope of predicate devices that are used in phototherapeutic applications such as the treatment of neonatal hyperbilirubinemia.

**Performance Data:**

The Resolve UVB Phototherapy System has the same indications for use as those cleared for the claimed UVB predicate devices. Performance data are included with the 510(k) to demonstrate that UVB emissions are within specification for the device and are the same or very similar to the spectra emitted by the predicate UVB devices. Additionally, information to support electrical safety, electromagnetic compatibility, biocompatibility, and functionality were included with the 510(k).

K072035

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**Conclusion:**

The Resolve UVB Phototherapy System is similar to other UVB emitting devices for localized treatment of dermatologic disease with the main difference being the source of the UV light. The Resolve device uses LEDs as a UVB light source. LEDs are used in other medical devices to provide light at spectra other than UVB. Since the Resolve UVB System has the same intended use, employs similar technologies, and is judged to pose no new questions of safety and effectiveness when compared with devices that have been cleared, Allux Medical considers it to be substantially equivalent to the legally marketed claimed predicate devices for the purpose of this 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Allux Medical, Inc.
% Mr. Lloyd H. Griese
VP, Quality Assurance
1430 O'Brien Drive, Suite F
Menlo Park, California 94025

OCT 16 2007

Re: K072035
Trade/Device Name: Resolve™ UVB Phototherapy System
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: FTC
Dated: September 14, 2007
Received: September 18, 2007

Dear Mr. Griese:

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.

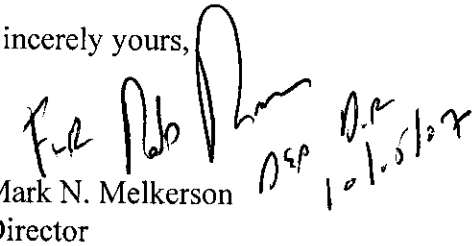
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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) 276-0120. 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,



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

Enclosure

## 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K072035

Device Name: Resolve™ UVB Phototherapy System

***Indications for Use:***

The Resolve™ UVB Phototherapy System is an ultraviolet light emitting medical device for localized phototherapeutic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. The Resolve™ UVB Phototherapy System is intended to be used with all Skin Types (I – VI).

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Page __ of ___

**510(k) Number** K072035