

### Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K132643

1. Prepared Date: Aug. 23, 2013

2. Sponsor Identification

Xuzhou Kernel Medical Equipment Co.,LTD.

Kernel Mansion,Economic Development District, Xuzhou,Jiangsu Province,China

Establishment Registration Number: Not yet registered

Contact Person: Zhengjun ZHANG

Position: General Manager

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3. Submission Correspondent

Ms. Diana Hong& Mr. Tarzan Wang

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IEC60601-1:2005+CORR.1:2006+CORR.2:2007 Medical electrical equipment Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2007 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests

#### 8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(s)
Product Code	<b>FTC</b>	<b>FTC</b>
Regulation Number	21 CFR 878.4630	21 CFR 878.4630
Intended Use	The UV phototherapy, model KN-4001/KN-4002/KN-4003/KN-4004/KN-4005/KN-4006, delivers ultraviolet (UV) light to targeted affected skin. It is intended for use, by or under the direction of a physician, for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI).	The DermaPal is a hand held ultraviolet light emitting fluorescent lamp. It is intended for use, by or under the direction of a physician, for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI).
Material	ABS	ABS
Sterile	N/A	N/A
Single Use	No	No
Energy Source	Fluorescent UV lamps	Fluorescent UV lamp
Safety	IEC 60601-1 / IEC 60601-1-2	IEC 60601-1 / IEC 60601-1-2
Biocompatibility	Non-Cytotoxicity Non-Irritation Non-Sensitization	Non-Cytotoxicity Non-Irritation Non-Sensitization
Mode of operation	Stationary base unit with hand held therapy wand or hand held device	Stationary base unit with hand held therapy wand
Features	UV Radiation Treatment System model KN-4001/KN-4002/KN-4003/KN-4004/KN-4005/KN-4006 delivers ultraviolet (UV) light to targeted affected skin, via	DermaPal is small enough to discreetly carry anywhere you go and plugs into any standard electrical outlet so you'll never miss a



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

January 30, 2014

Xuzhou Kernel Medical Equipment Company, Ltd.  
% Ms. Diana Hong  
Mid-Link Consulting Company, Ltd.  
P.O. box 120-119  
Shanghai, Shanghai 200120  
CHINA

Re: K132643

Trade/Device Name: UV Phototherapy  
Regulation Number: 21 CFR 878.4630  
Regulation Name: Ultraviolet lamp for dermatologic disorders  
Regulatory Class: Class II  
Product Code: FTC  
Dated: December 25, 2013  
Received: December 30, 2013

Dear Ms. Hong:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**David Krause -S**

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Section 2 Indications for Use

510(k) Number: K132643

Device Name: UV phototherapy

### Indications for Use:

The UV phototherapy, model KN-4001/KN-4002/KN-4003/KN-4004/KN-4005/KN-4006, delivers ultraviolet (UV) light to targeted affected skin. It is intended for use, by or under the direction of a physician, for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI).

**PRESCRIPTION USE**  
(Part 21, CFR 801 Subpart D)

OR

**OVER-THE-COUNTER USE**  
(21 CFR 801 Subpart C)

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

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Concurrence of CDREH, Office of Device Evaluation (ODE)

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(Division Sign-off) for BSA

Division of Surgical Devices

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