July 10, 2018

Uvbiotek, LLC
% Jinghua Zhou
Regulation Control Manager
Guangzhou Junyi Information Technology Co., Ltd.
Room 215, Huaming Building, Chebei Road
Guangzhou, 511660 Cn

Re: K180900
Trade/Device Name: LED Light Therapy Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: OLP
Dated: April 6, 2018
Received: April 13, 2018

Dear Jinghua Zhou:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Binita S. Ashar -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
LED Light Therapy Device

Indications for Use *(Describe)*
The LED Light Therapy Device is indicated for the treatment of mild to moderate inflammatory acne.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5 - 510(k) Summary

Date of Summary Preparation: April 3, 2018

1. Submitter's Identifications

Submitter's Name: UVBIOTEK, LLC
Address: 3 Depot Street, Hudson Falls, NY 12839, United States
Contact Person: Dave Oberhelman
Contact Title: Plant Manager
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Telephone: 518-747-3310
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2. Correspondent's Identifications

Correspondent's Name: Guangzhou Junyi Information Technology Co., Ltd.
Address: Room 215, Huaming Building, Chebei Road, Guangzhou, P.R. China
ZIP Code: 511660
Contact Person: Jinghua Zhou
Contact Title: Regulation Control Manager
Contact E-mail Address: kernel_2016@126.com
Telephone: +86-20-82329549
Fax: +86-20-82329549

3. Name of the Device

Device Classification Name: Over-The-Counter Powered Light Based Laser For Acne
Product Name: Over-The-Counter Powered Light Based Laser For Acne
Trade Name: LED Light Therapy Device
Model: KN-7000C, KN-7000C2
Classification Panel: General & Plastic Surgery
Product Code: OLP
Device Classification: Class II

4. The Predicate Devices

K153081 Clear Bi-Light
K081307 OmniLux Clear U

5. Device Description

The LED Light Therapy Device is a lightweight device which uses specific wavelengths of light, produced by light emitting diodes (LEDs), to manage aesthetic conditions. The device produces light in the red light region of the spectrum (633±10nm) and/or in the blue light region of the spectrum (417±10nm), intended to help reduce the appearance of mild to moderate acne.

This device is made up of a main unit and therapy head. The light gathering cover is also referred to as the snoot. The snoot helps to establish the correct treatment distance.

Description for KN-7000C:
The device uses 48 LED cold light sources, and uses an external removable single cell lithium ion battery for power, with a continuous usage time of 120 minutes. It can be charged using a power adapter.

The LED information:

Items	Red head	Blue head
LED numbers	48	48
Total spectrum peak wavelength	633nm±10nm	417nm±10nm
Total effective irradiance	45mW/cm² ± 5mW/cm²	25mW/cm² ± 5mW/cm²
Total luminous power	1.3W	0.78W
Total energy fluxes	9J/cm²	5.4J/cm²

The specification table is as below:

SPECIFICATIONS

Model	KN-7000C
Safety classification	Class II, has internal power source.
Operating mode	Continuous operation
IP rating	IP22
Adapter model number	LXCP12-005200DEG, Input: 100-240V a.c. 50/60Hz, 0.5A max. Output: 5V d.c. 2A
Main unit	input: 5V d.c. 2A/Internal battery: 3.6Vd.c. 2200mAh
Internal battery specification	CR18650-22F 3.6V d.c. 2200mAh
Working environment	Temperature: 5～40℃, 41-104° F Relative humidity: 15%-90% Barometric pressure: 700hPa～1060hPa
Transport and storage environment	Temperature: -25 to 70℃, -13 to 158° F Relative humidity: ≤90 % Barometric pressure: 500～1060hPa
Structural configuration	Handheld
Display style	No
Effective configuration area	26cm²±10%
Irradiance distance	Hold treatment face in contact with skin
Spectrum peak wavelength	Red light 633nm±10nm Blue light 417nm±10nm
Effective irradiance	Red light 45±5mW/cm² Blue light 25±5mW/cm²
Timing and functions	The device has a timer, with a timing error of less than ±2% of the pre-set value.

	The device has the function of manually stopping irradiation output.
Operation noise	Not exceed 60dB(A)

The list of accessories

No.	Name	Specifications	Quantity	Unit
1	Adapter	LXCP12-005200DEG	1	Piece
2	Protective eyewear	YH-8	1	Pieces
3	Manual	User Manual	1	Copy
4	Certificate	KN-7000C	1	Copy

Description for KN-7000C2:

The device uses 8 LED cold therapy heads and has high stability, strong uniformity, and a long lifespan. It uses an external removable single cell lithium ion battery for power, with a continuous usage time of 4.5 hours. It can be charged using a power adapter.

The LED information:

Items	Red head	Blue head
LED numbers	8	8
Total spectrum peak wavelength	633nm±10nm	417nm±10nm
Total effective irradiance	65mW/cm² ± 5mW/cm²	35mW/cm² ± 5mW/cm²
Total luminous power	0.28W	0.16W
Total energy fluxes	8.4J/cm²	4.8J/cm²

The specification table is as below:

SPECIFICATIONS

Model	KN-7000C2
Safety classification	Class II, has internal power source.
Operating mode	Continuous operation
IP rating	IP22
Adapter model number	LXCP12-005200DEG, Input: 100-240V a.c. 50/60Hz, 0.5A max. Output: 5V d.c. 2A
Main unit	input: 5V d.c. 2A/Internal battery: 3.6Vd.c. 2200mAh
Internal battery specification	CR18650-22F 3.6V d.c. 2200mAh
Working environment	Temperature: 5～40℃, 41-104° F Relative humidity: 15%-90% Barometric pressure: 700hPa～1060hPa
Transport and storage environment	Temperature: -25 to 70℃, -13 to 158° F Relative humidity: ≤90 % Barometric pressure: 500～1060hPa

Structural configuration	Handheld
Display style	OLED display
Effective configuration area	4cm^2±10%
Irradiance distance	Hold treatment face in contact with skin
Spectrum peak wavelength	Red light 633nm±10nm blue light 417nm±10nm
Effective irradiance	Red light 65±5mW/cm^2 blue light 35±5mW/cm^2
Timing and functions	The device has a timer, with a timing error of less than ±2% of the pre-set value. The device has the function of manually stopping irradiation output.
Operation noise	Not exceed 60dB(A)

The list of accessories

No.	Name	Specifications	Quantity	Unit
1	Adapter	LXCP12-005200DEG	1	Piece
2	Protective eyewear	YH-8	1	Pieces
3	Manual	User Manual	1	Copy
4	Certificate	KN-7000C2	1	Copy

6. Intended Use of Device

The LED Light Therapy Device is indicated for the treatment of mild to moderate inflammatory acne.

7. Summary of Substantial Equivalence

Table 1 Comparison to Predicate Device for KN-7000C

	Proposed Device	Predicate device	Predicate device	Comparison
510k Number	------	K153081	K081307	------
Product Code	OLP	OLP	OLP	Same
Proprietary Name	LED Light Therapy Device	Clear Bi-Light	OmniLux Clear U	------
Model	KN-7000C	/	/	------
Manufacturer	Xuzhou Kernel Medical Equipment Co., Ltd.	Michael Todd, LP	Photo Therapeutics Inc	------
Indications for Use	The LED Light Therapy Device is indicated for the treatment of mild to moderate inflammatory acne.	The Clear Bi-Light is indicated for the treatment of mild to moderate inflammatory acne.	Indicated to treat mild to moderate acne on the face.	Same
OTC or Rx	OTC	OTC	OTC	Same
Energy source	LED	LED	LED	Same
Treatment heads	Separate blue and red, treatment heads	Separate blue and red, treatment heads	Blue and Red in same head, chosen using selector switch	Same
Wavelength(s) (nm)	417±10 633±10	405-420 630-660	415±5 633±6	Substantially equivalent Wavelengths are in the blue and red spectrums.
Treatment control	“ ►/■ ” button to turn the irradiator on or off for therapy, hold shoot in contact with skin	On/off button puts device in standby mode. Contact sensor in treatment face, touching device to face activates LEDs.	Three position switch: Off – Blue - Red	Substantially equivalent KN-7000C and Clear Bi-Light have on/off button. Contact sensor in proposed device is the same as in the Clear

				Bi-Light.
Treatment indicator	Indicator will light up when treatment; the indicator is yellow when charging; the indicator light is green when it is charged fully.	Indicator light-solid green while treatment is in process; blinking indicates low battery. Audio signal; long beep when power is turned on, short beep every 30 seconds during treatment; long beep at end of 3 minute cycle.	No	Indicators light substantially equivalent to the Clear Bi-Light. Indicators light can indicate related status of the device.
Treatment timer	The recommended therapy times are 3 minutes per area after which device returns to standby mode. Must press treatment face against skin to reactivate lights.	Up to 3 minutes treatment per area after which device returns to standby mode. Must press treatment face against skin to reactivate lights.	No	Same as the Clear Bi-Light.
Treatment regimen	Hold treatment face in contact with skin. Apply blue light for 3minutes per skin area, followed by red light for 3 minutes per skin area. Can be used daily.	Hold treatment face in contact with skin. Apply blue light for up to 3minutes per skin area, followed by red light for up to 3 minutes per skin area. Can be used daily.	Alternate treatments of blue and red light twice a week for 20 minutes per treatment.	Same as the Clear Bi-Light.
Dose rate (mW/cm^2)	25±5(blue) 45±5(red)	31.1(blue) 54.6(red)	40(blue) 70(red)	Substantially equivalent-within dose rate ranges of predicate devices.
Treatment face area(cm^2)	26±10%	20	28.7	Substantially equivalent-within size ranges of predicate devices.

Max treatment temperature(℃)	36.8(blue) 36.5(red)	38(blue) 40(red)	39-43	Substantially equivalent-within temperature ranges of predicate devices
Microprocessor controlled	Yes	Yes	Unknown	Same as the Clear Bi-Light.
Handheld	Yes	Yes	Yes	Same
Patient contacting material	Rigid ABS Clear polycarbonate lens cover	Rigid ABS Clear polycarbonate lens cover	Rigid ABS	Same
Power supply	Adapter model number: LXCP12-005200DEG, Input: 100-240V a.c. 50/60Hz, 0.5A max. Output: 5V d.c. 2A Main unit input: 5V d.c. 2A/Internal battery: 3.6Vd.c. 2200mAh Internal battery specifications: CR18650-22F 3.6V d.c. 2200mAh	Lithium-ion rechargeable battery AC charger: 100-240V at 50-60 Hz, 500mA	A separate, universal, power supply converts mains AC power to the DC power required	Substantially equivalent to the Clear Bi-Light. All devices have power adapter.
Dimensions	257mm×165mm×70mm (10.1in×6.5in×2.8in)	6.4cm×3.5cm×14.6cm (2.5in×1.4in×5.7in)	6cm×4cm×12cm (2.4in×1.6in×4.7in)	Substantially equivalent Both are light-weight, hand held devices.
Weight	174g(6.1 oz)	107.1g(3.8 oz)	Unknown	Substantially equivalent Both are light-weight, hand held devices.
Standard	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	Same All devices meet the requirements of effectiveness, safety and biocompatibility.

	IEC 62471 ISO 10993-1 ISO 10993-5 ISO 10993-10	IEC 62471 ISO 10993-1 ISO 10993-5 ISO 10993-10	IEC 62471 ISO 10993-1 ISO 10993-5 ISO 10993-10	

Table 2 Comparison to Predicate Device for KN-7000C2

	Proposed Device	**Predicate device**	**Predicate device**	**Comparison**
510k Number	------	K153081	K081307	------
Product Code	OLP	OLP	OLP	Same
Proprietary Name	LED Light Therapy Device	Clear Bi-Light	OmniLux Clear U	------
Model	KN-7000C2	/	/	------
Manufacturer	Xuzhou Kernel Medical Equipment Co., Ltd.	Michael Todd, LP	OmniLux Clear U	------
Indications for Use	The LED Light Therapy Device is indicated for the treatment of mild to moderate inflammatory acne.	The Clear Bi-Light is indicated for the treatment of mild to moderate inflammatory acne.	Indicated to treat mild to moderate acne on the face.	Same
OTC or Rx	OTC	OTC	OTC	Same
Energy source	LED	LED	LED	Same
Treatment heads	Separate blue and red, treatment heads	Separate blue and red, treatment heads	Blue and Red in same head, chosen using selector switch	Same as the Clear Bi-Light (both offer separate blue and red light treatment heads).
Wavelength(s) (mm)	417±10 633±10	405-420 630-660	415±5 633±6	Substantially equivalent Wavelengths are in the blue

				and red spectrums
Treatment control	“►/■” button to turn the irradiator on or off for therapy, The treatment head should rest against the skin area to be treated.	On/off button puts device in standby mode. Contact sensor in treatment face, touching device to face activates LEDs.	Three position switch: Off – Blue - Red	Substantially equivalent KN-7000C and Clear Bi-Light have on/off button. Contact sensor in proposed device is the same as in the Clear Bi-Light.
Treatment indicator	Indicator will light up when treatment; the indicator is yellow when charging; the indicator light is green when it is charged fully.	Indicator light-solid green while treatment is in process; blinking indicates low battery. Audio signal; long beep when power is turned on, short beep every 30 seconds during treatment; long beep at end of 3 minute cycle.	No	Indicators light substantially equivalent to the Clear Bi-Light. Indicators light can indicate related status of the device.
Treatment timer	The recommended therapy times are 2 minutes per area after which device returns to standby mode. Must press treatment face against skin to reactivate lights.	Up to 3 minutes treatment per area after which device returns to standby mode. Must press treatment face against skin to reactivate lights.	No	Substantially equivalent to the Clear Bi-Light. Both devices limit treatment to within 3 minutes.
Treatment regimen	Hold treatment face in contact with skin. Apply blue light for 2minutes per skin area, followed by red light for 2 minutes per skin area. Can be used daily.	Hold treatment face in contact with skin. Apply blue light for up to 3minutes per skin area, followed by red light for up to 3 minutes per skin area. Can be used daily.	Alternate treatments of blue and red light twice a week for 20 minutes per treatment.	Substantially equivalent to the Clear Bi-Light. Both devices limit treatment to within 3 minutes.
Dose rate	35±5(blue)	31.1(blue)	40(blue)	Substantially

(mW/cm²)	65±5(red)	54.6(red)	70(red)	equivalent-within dose rate ranges of predicate devices.
Treatment face area(cm²)	4±10%	20	28.7	Substantially equivalent-within size ranges of predicate devices
Max treatment temperature(℃)	37.5(blue) 37.0(red)	38(blue) 40(red)	39-43	Substantially equivalent-within temperature ranges of predicate devices
Microprocessor controlled	Yes	Yes	Unknown	Same
Handheld	Yes	Yes	Yes	Same
Patient contacting material	Rigid ABS Clear polycarbonate lens cover	Rigid ABS Clear polycarbonate lens cover	Rigid ABS	Same
Power supply	Adapter model number: LXCP12-005200DEG, Input: 100-240V a.c. 50/60Hz, 0.5A max. Output: 5V d.c. 2A Main unit input: 5V d.c. 2A/Internal battery: 3.6Vd.c. 2200mAh Internal battery specifications: CR18650-22F 3.6V d.c. 2200mAh	Lithium-ion rechargeable battery AC charger: 100-240V at 50-60 Hz, 500mA	A separate, universal, power supply converts mains AC power to the DC power required	Substantially equivalent to the Clear Bi-Light. All devices have power adapter.
Dimensions	231mm×159mm×68mm (9.1in×6.3in×2.7in)	6.4cm×3.5cm×14.6cm (2.5in×1.4in×5.7in)	6cm×4cm×12cm (2.4in×1.6in×4.7in)	Substantially equivalent All devices are light-weight, hand held devices.
Weight	122g(4.3 oz)	107.1g(3.8 oz)	Unknown	Substantially equivalent to the Clear Bi-Light Both are

				light-weight, hand held devices.
Standard	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 62471 ISO 10993-1 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 62471 ISO 10993-1 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 62471 ISO 10993-1 ISO 10993-5 ISO 10993-10	Same All devices meet the requirements of effectiveness, safety and biocompatibility.

8. Substantial Equivalence discussion:

The indication for use of the KN-7000C LED Light Therapy Device and KN-7000C2 LED Light Therapy Device are the same as that for the predicate devices. Most technical specifications of the KN-7000C LED Light Therapy Device and KN-7000C2 LED Light Therapy Device are either the same or substantially equivalent as compared to the predicate devices. There are no technological differences that raise new or different questions of safety or effectiveness.

9. Non-Clinical Tests Performed:

The following non-clinical testing was provided in this 510(k):

Biocompatibility Testing – The skin contacting materials of the device were subjected to biocompatibility testing per ISO 10993-1:2009/C1:2010, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing," for devices in contact with intact skin, including in vitro cytotoxicity, skin sensitization, and skin irritation. All tests passed. The tests comply with the applicable requirements of the following standards:

ISO10993-5:2009, Biological evaluation of medical devices-Part 5: tests for in vitro cytotoxicity.

ISO10993-10:2010, Biological evaluation of medical devices-Part10: tests for irritation and skin sensitization.

Electrical Safety and Electromagnetic Compatibility Testing – The KN-7000C LED Light Therapy Device and KN-7000C2 LED Light Therapy Device have been tested and comply with the applicable requirements of the following standards for medical devices used in the home environment:

● AAMI/ANSI ES60601-1: 2005/(R)2012 and A1:2012,, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance

● IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests

● IEC 60601-1-11:2015 Medical electrical equipment-Part 1-11: General requirements for basic safety and essential performance - Collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

● IEC 60601-2-57:2011 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests

Photobiological Safety Testing – The KN-7000C LED Light Therapy Device and KN-7000C2 LED Light Therapy Device have been tested and comply with IEC 62471:2006, Photobiological safety of lamps and lamp systems, 1st edition. This IEC standard incorporates the principles of the following ANSI IESNA recommended practices:

● RP 27.1:2005 Recommended practice for photobiological safety for lamps and lamp systems - General requirements

● RP 27.2:2000 Recommended practice for photobiological safety for lamps and lamp systems - Measurement techniques

● RP-27.3:2007 Recommended practice for photobiological safety for lamps and lamp systems – Risk group classification and labeling

Software Verification and Validation – Software documentation consistent with moderate level of concern was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

10. Usability Study:

The KN-7000C LED Light Therapy Device and KN-7000C2 LED Light Therapy Device were performed usability study separately by similar methods.

Usability study summary of KN-7000C LED Light Therapy Device:

This usability Study was started on 1/7/2018 at 3 Depot Street, Hudson Falls, NY, USA.

It was conducted by Dave Oberhelman, Plant/Compliance Manager, UVBioTek

The study was completed on 2/1/2018.

The required number of participants was obtained through networking, social media and advertising in the local newspaper.

All of the participants were able to correctly answer the questions as listed in Appendix 1 and Appendix 2 All the participants were able to self select whether or not the product was correct for them. Some of the participants did not have acne but they would purchase the product for their children who did have acne.

Most of the participants offered suggestions to change the wording to make different parts of the manual easier to read and understand.

The original user manual for this study is in section 5 of this binder. The participant improved version is in section 7 of this binder.

The packaging materials used in the 1st part of this study will be e-mailed to Jonny Chen, of Kernel Medical, because they will not fit in this binder.

The following are samples of some of the suggestions the participants made to make the user manual easier to understand. Reference to page numbers applies to the new updated version of the manual.

State that the treatment heads have color dots on the back to identify what color LED is placed inside the treatment head Page 6 & 7.

List “How to take a treatment” in the table of contents.

Define what a snoot is. Page 9.

Remove 1% mild detergent and replace with diluted, non-corrosive, mild detergent Page 23.

State "Press and Hold" the power button. Page 14.

State at the very beginning that this device has two different color treatment heads. Page 1.

Change “operation mode” to "treatment time selection". Page 10

Change “work mode" button to "treatment time selector”. Page 9

State "start treatment with blue LED treatment head". Page 14

State "Install the red treatment head and complete the treatment”. Page 15

Define what it means to be insensitive to heat. Add (can not feel heat). Page 1

State that the time setting and treatment start must be completed with in 30 seconds or the unit will shut off to conserve the battery. Page 14

Move the LED Life statement to page 20.

Usability study summary of KN-7000C2 LED Light Therapy Device:

This usability Study was started on 1/20/2018 at 3 Depot Street, Hudson Falls, NY, USA.

It was conducted by Dave Oberhelman, Plant/Compliance Manager, UVBioTek

T he study was completed on 2/4/2018.

The required number of participants was obtained through networking, social media and advertising in the local newspaper.

All of the participants were able to correctly answer the questions as listed in Appendix 1 and

Appendix 2 All the participants were able to self select whether or not the product was correct for them. Some of the participants did not have acne but they would purchase the product for their children who did have acne.

This study was started after the study for the 7000C was started The User Manuals, Warnings, Cautions, Contraindications and package artwork are very similar. Most of the improvements obtained by the 7000C study were incorporated in to the artwork and user manual for the 7000C2, before the 7000C2 study started. The participants did not have any suggestions for improvements because all the material was easy to understand.

Some of the participants noticed that question # 10 in Appendix # 2 did not have a correct answer. Answer 'B" showed "⏻" but is should have shown "⏻/☼". These participants were very good evaluators.

The original user manual for this study is in section 5 of this binder. The participant improved version is in section 7 of this binder.

The packaging materials used in the 1st part of this study will be e-mailed to Jonny Chen, of Kernel Medical, because they will not fit in this binder.

11. Conclusion:

Based on comparing to predicate device, the proposed device of KN-7000C and KN-7000C2 are determined to be Substantially Equivalent (SE) to the predicate device, in respect of safety and effectiveness.

--- End of this section ---