DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 6, 2017

Philips Electronics Nederland B.V.
Ms. Gaozhen Hang
Senior Regulatory Affairs Specialist
High Tech Campus 5
Eindhoven, 5656 AE
The Netherlands

Re: K171055
Trade/Device Name: Philips BlueControl
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: ONE
Dated: April 7, 2017
Received: April 10, 2017

Dear Ms. Hang:

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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -S3

For 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)*

K171055

Device Name
Philips BlueControl

Indications for Use *(Describe)*

The Philips BlueControl is intended to emit energy in the blue region of the spectrum, is generally indicated to treat dermatological conditions and specifically indicated to treat mild psoriasis vulgaris.

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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510(k) Summary

The summary of safety and effectiveness information is included in this submission in accordance with the Safe Medical Device Act of 1990 and 21 CFR §807.92.

I. **SUBMITTER** Philips Electronics Nederland B.V.
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Date Prepared: April 7, 2017

II. DEVICE

Trade Name:	Philips BlueControl
Common/Classification Name:	Powered Light Based Non-Laser Surgical Instrument
Regulatory Class:	II
Product Code, CFR:	ONE
Review Panel:	General and Plastic Surgery (79)

III. PREDICATE DEVICE

1. Omnilux Clear-U, K081307
2. Omnilux Blue, K030883

The predicates have not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Philips BlueControl is a rechargeable battery-operated, wearable device for delivery of blue light to treat mild psoriasis vulgaris. It is a prescription device designed for home use.

The Philips BlueControl is sold as a kit, which contains the following items:

- Components:
  - BlueControl Device
  - Fixation Strap (Device Holder and Slings)
  - Power Supply (USB Cable, Adapter and Charger)
- Accessory:

    - Carrying Case
- Instructions for Use

V. INDICATIONS FOR USE

The Philips BlueControl is intended to emit energy in the blue region of the spectrum, is generally indicated to treat dermatological conditions and specifically indicated to treat mild psoriasis vulgaris.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISCS WITH THE PREDICATE

Information for predicate devices was obtained from publicly available sources, including the 510(k) Summaries and device instruction manuals.

Item	Subject Device: Philips BlueControl	Primary Predicate: Omnilux Clear-U K081307	Secondary Predicate: Omnilux Blue K030883	Comparison
Energy Source	LED	LED	LED	Same
Output Wavelength(s) (nm)	452+/-7	Blue: 415 +/- 5 Red: 633 +/- 6	415 +/- 5	Similar wavelengths in the blue light spectrum
Dose Rate/Intensity (mW/cm^2)	40 +/- 5	40	40	Same
Average Dose (J/ cm^2)	72 +/- 9 (maximum dose: 90)	40 (blue) 70 (red)	48 (dosage range: 1-150)	The average treatment dose is within dose range of the predicates.
Method of Delivery	Blue light treatment administrated through the lower housing.	Blue light treatment administrated through treatment head.	Blue light treatment administrated through treatment head.	Same
Treatment Regimen	A full course of the treatment consists of 4 weeks of daily treatment 5-7 times a week followed by 8 weeks of treatment 3 times a week. A single treatment takes approximately 30 minutes with or without interruptions.	Alternate treatments of blue and red light twice a week for 20 minutes per treatment for 4 weeks. Forearm test for 20 minutes before starting treatment regime.	One treatment consists of 20 minutes at standard dose. The full treatment course consists of 8 treatments.	Similar in treatment time per day.

Item	Subject Device: Philips BlueControl	Primary Predicate: Omnilux Clear-U K081307	Secondary Predicate: Omnilux Blue K030883	Comparison
Treatment Control(s)	On/off button puts device in standby mode. Infrared sensor on the treatment face measures the skin temperature. It senses the presence of the skin and activates LEDs.	Three position switch: Off-Blue- Red	The control unit consists of an LCD and keyboard together with the control electronics. The user interface software allows the operator to access and control all device functions.	All devices have on/off switches. The sensor provides equivalent or better safety assurance.
Treatment Indicator(s)	<u>Visual signal:</u> -flashing blue- waiting for skin detection -solid blue -treatment is in progress; - flashing blue slowly after recovery from skin overheated (exceeds 43 °C) until the skin cool off. -solid orange- device is overheated: exceeds 51 °C (device switches off); -flashing green-charging -solid green-fully charged -flashing and solid red- battery empty <u>Audio signal:</u> -one (1) beep- connected to power supply - a two (2) tones beep- the treatment starts - a two (2) tones beep- the treatment ends	None	Unknown	The treatment light and audio indicators provide equivalent or better safety assurance comparing to Omnilux Clear-U.

Item	Subject Device: Philips BlueControl	Primary Predicate: Omnilux Clear-U K081307	Secondary Predicate: Omnilux Blue K030883	Comparison
	-a long 3-second beep- device overheated (device switches off) -three (3) beeps- battery empty			
Treatment Timer	Yes- 30 minutes treatment per area after which device automatically switches off.	None	Unknown	The treatment timer provides equivalent or better safety assurance comparing to Omnilux Clear-U.
Treatment Surface Area (cm^2)	38	28.7	525 (LED head active dimensions)	Comparable in size with Omnilux Clear-U.
Max Treatment Temperature (°C)	43 (skin) 51 (device)	39-43	Unknown	Similar in temperature limit with Omnilux Clear-U
Patient Contacting Materials	Clear polycarbonate LED cover OEKO-TEX®-certified fabric device holder and straps	Rigid ABS	NA	Biocompatible materials used in both the BlueControl and Omnilux Clear-U.
Power Supply	3.7 V/rated capacity 6.1Wh lithium-ion rechargeable battery. AC charger: Input: 100-240V at 50-60 Hz	"A separate universal, power supply converts main AC power to the DC power required"	Wall power	The differences in power supply provide equivalent or better safety assurance.

Item	Subject Device: Philips BlueControl	Primary Predicate: Omnilux Clear-U K081307	Secondary Predicate: Omnilux Blue K030883	Comparison
	Output: 5V DC and 1A/7W			
Dimensions (height x width x depth in cm)	12.5 x 7.72 x 2.28	12 x 6 x 4	37 x 18 x 49	Comparable in size with Omnilux Clear-U
Weight	5.9 oz. (without fixation strap) 7.8 oz. (with fixation strap)	Less than 1 pound	26.4 lb.	Similar in weight with Omnilux Clear-U
Treatment Head Design	40 Blue LEDs	30 Blue LEDs	Number of LEDs not available	Similar in design with Omnilux Clear-U
Principles of Operation	Wearable	Handheld	Desktop	All devices are positioned over the specific skin treatment area to deliver light energy. .

The indications for use statement for the Philips BlueControl is not identical to the predicate devices; however the differences in the disease treated do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. The technical specifications of the Philips BlueControl device are either 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.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing
The skin contacting materials of the device (lower housing, device holder and strap) were evaluated for biocompatibility per ISO 10993-1 (2009): *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing," for devices in contact with intact skin, including cytotoxicity, dermal sensitization, and dermal irritation*.

Electric Safety and Electromagnetic Compatibility Testing
The Philips BlueControl has been tested and complies with the applicable requirements of the following standards for medical devices used in the home environment:

- IEC 60601-1:2006 Medical Electrical Equipment - Part 1: General Requirements for Safety, 3rd edition
- IEC 60601-1-11: 2010 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: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
- IEC 60601-1-2: 2007 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Photobiological Safety Testing
The Philips BlueControl has been tested and complies with IEC 60601-2-57 (2011): *Medical Electrical equipment part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use, 1st edition* and IEC 62471 (2006-07): *Photobiological safety of lamps and lamp systems, 1st edition*. Those IEC standards incorporate the measurement techniques 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

Other Bench Testing
Thermal safety and reliability testing has also been conducted to verify the risk controls implemented for the Philips BlueControl are effective to mitigate the hazards identified.

Software Verification and Validation Testing
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.

Clinical Studies
To support the proposed indication for use, two clinical studies of N=50 have been performed in Europe per ISO 14155: *Clinical investigation of medical devices for human subjects -- Good clinical practice*. In both studies, psoriasis severity was evaluated using the Local Psoriasis Area and Severity Index (LPASI), a modified version of the validated PASI. No serious adverse events were considered related to any of the studied treatment regimen.

One clinical study was conducted on 23 enrolled subjects who received blue light treatment at 200 mW/cm^2 setting for their mild plaque psoriasis. The patients were treated with blue light for 30 minutes per plague per treatment for 12 weeks followed by a 4-week follow up period without treatment. During the full course of 12-week treatment, the 30-minute blue light treatment was performed daily (5 to 7 treatments per week) for the first 4 weeks, followed by 8 weeks with 3 treatments per week. The plaque severity was evaluated using the LPASI. The primary endpoint, change from baseline (CfB) of the LPASI at week 12, revealed a significant improvement of the treated compared to the control plaques (ΔCfB: -0.92 ± 1.10, $p = 0.0005$, t test; $p = 0.0006$, Wilcoxon signed-rank test; mean 95% CI –1.38, –0.45). The mean change from baseline to week 12 was -2.38 (-3.02 to -1.73) in the treated plaque and -1.46 (-2.13 to -0.79) in the control plaque. All 16 adverse events observed during the study were evaluated. No serious adverse events were reported. None of the adverse events were device-related or treatment-related. The hyperpigmentation (tanning) of the treated skin was expected and reported by some of the study participants. The tanning effect reduced within a few days after completion of the treatment cycle. No other device-related adverse effects of the device are observed.

The results of these studies demonstrate the 12-week treatment cycle of BlueControl reduces the severity of mild psoriasis vulgaris.

VIII. CONCLUSIONS

The Philips BlueControl and its predicates emit energy in the blue region of the light spectrum to treat dermatological conditions. The performance achieved by these devices uses nearly identical power intensities and wavelengths. Both the Philips BlueControl and the primary predicate are intended to be placed directly on the skin to provide the light energy. The primary predicate device is cleared for over-the- counter home use, and the

Philips BlueControl is a prescription home use device. The intended patient population for the Philips BlueControl fall within the intended use of the secondary predicate device, which is generally indicated to treat dermatological conditions for prescription use. To support the specific indication for use, the clinical testing performed using Philips BlueControl demonstrates its effectiveness for treatment of mild psoriasis vulgaris in adult patients.