DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 10, 2015

National Biological Corporation
Ms. Jennifer Cartledge
REU Associates Incorporated
409 Woodridge Drive
Seneca, South Carolina 29672

Re: K150912
Trade/Device Name: HOUVA-Net Control System
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: Class II
Product Code: FTC
Dated: June 15, 2015
Received: June 16, 2015

Dear Ms. Cartledge:

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" (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 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 yours,

Jennifer R. Stevenson -S

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)*

K150912

Device Name
HOUVA-Net Control System

Indications for Use *(Describe)*
The Houva-NET Control System is a therapeutic product designed for individuals who require specific Ultraviolet radiation therapy for the treatment of psoriasis and vitiligo.

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

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5. 510(k) Summary

Type of submission: Traditional 510(k); this is the first submission for this device.

Date of Submission: March 28, 2015

Preparation of Submission: This submission has been prepared by J. Cartledge on behalf of National Biological Corporation.

Name and Address of Manufacturer and 510(k) Owner:

National Biological Corporation
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Establishment registration number: 1521608
Contact: Lynn Keller, Director of Regulatory Affairs, Quality and Engineering

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Device Identification

Trade Name:	***Houva V with Houva-NET Control System***
Model number:	***Houva V***
Common names:	Ultraviolet lamp for dermatologic disorders
Classification(s) of the device:	Light, Ultraviolet, Dermatological, 21CFR 878.4630 Product Code: FTC Classification Panel: General and Plastic Surgery Class II

Equivalent legally marketed devices:

- *Houva III Phototherapy System with PhotoSense II™* (K041212)

The Daavlin *Smart Touch Multi-Machine Software* (K110912) provides an example of a cleared device considering a single control board managing multiple phototherapy devices via a single control board, *Smart Touch UV Therapy Multiple Machine*. Under this pre-market clearance, the *Smart Touch UV Therapy Multiple Machine* utilizes a single control board to manage operation of multiple phototherapy devices.

Device Description:

The *Houva V with Houva-NET Control System* is simply the integration of the new *Houva-NET Control System* software, into the predicate device, the *Houva III Phototherapy System with PhotoSense II™.* The *Houva -NET Control System* software is utilized to monitor multiple phototherapy devices from a single computer, the *Houva-NET* Central Computer. The central computer may be used to monitor mulitiple phototherapy devices from one central location. A custom built interface board, 5PCB-040, supplied by National Biological Corporation is installed in each phototherapy device. An "off-the shelf" replacement is not possible and a replacement may only be obtained from National Biological Corporation. Schematics are located in the Device Description of this 510(k) submission, Section 11.

The integration of the new *Houva-NET Control System* software into the predicate device, the *Houva III Phototherapy System with PhotoSense II™*, results in the modified system or the *Houva V with Houva-NET Control System.* The modification, as compared to the predicate, is limited to the replacement of the PhotoSense II Controller with the new *Houva-NET Control.* The *Houva V with Houva-NET Control System* software is designed to provide Ultraviolet A (UVA) and/or Ultraviolet B (UVB) radiation treatments in the same manner as the predicate device.

The Houva-NET Control System may be retrofitted into any *Houva Phototherapy Systems*, constructed in the same design configuration as the predicate device, *Houva III Phototherapy System with PhotoSense II™* (K041212) and utilizing identical energy source (UV Lamps) and materials of identical composition. The *Houva V with Houva-NET Control System's* only variation from the predicate device is that the control system hardware and software have been updated to control multiple phototherapy units. The intended use, general and specific indications for use, spectral output, mode of operation, labeling, treatment area, and general operating principals of the *Houva V with Houva-NET Control System* are the same as those of the predicate. Additionally, the use of control system software and interface board to manage multiple phototherapy devices have already received FDA market clearance under K110912 integrated into the Daavlin *Smart Touch Multi-Machine Software.*

Intended Use:

The *Houva-NET Control System* may also be integrated into the following *HOUVA* models:

- *Houva II UVA (K885025)*
- *Houva II UVB (K885026)*
- *Houva II* UVA/UVB (K885029)

- *Houva III Phototherapy System with PhotoSense II™* (K041212)
- *Houva III/IV Phototherapy System with PhotoSense II™*

  NOTE- the *Houva III* and *Houva III/IV* Phototherapy System are identical in every way apart from a Marketing Name change; therefore, the clearance for *Houva III* also applies to the *Houva III/IV* system.

Additionally, the *Houva -NET Control* System is intended as a retro-fit kit for the following Daavlin Distributing Company models:

- 3 Series SP Models (K063621):
- 3 Series PC Models (K063621):
- 3 Series X Models (K042502):
- Spectra (K828654):

The integration of the *Houva -NET Control* System as a retro-fit kit for the above noted models has been assessed through extensive verification and validation testing as documented in Section 18 of this submission, Section 18C, HN-502 Daavlin System Test. This testing confirms that retrofitting the above noted models with the *Houva -NET Control* System results in an equivalent system as compared to the *Houva III (III/IV) Phototherapy System with PhotoSense II™* predicate.

The Indication for Use for the *Houva V with Houva -NET Control System* is identical to that of the predicate, the *Houva III Phototherapy System with PhotoSense II™* and is as follows:

> *The Houva V with Houva -NET Control System is a therapeutic product designed for individuals who require specific Ultraviolet radiation therapy for diagnosed skin disorders.*

The *Houva-NET Control* System will be applicable to additional phototherapy systems once the complete verification and validation are completed for each individual system.

Comparison to Predicate Device

The modified *Houva V with Houva-NET Control System is* substantially equivalent to the cleared *Houva 3 Phototherapy System with PhotoSense II™* in terms of intended use, technology, and performance. Table 5-1 compares the proposed *Houva -NET Control System* with the predicate.

Table 5-1: Substantial Equivalence Table

Characteristic	***Houva V with Houva-NET Control System***	***Houva 3 Phototherapy System with PhotoSense II™***	***Comparison***
Intended Use **Target population** **Indication for Use**	"The Houva-NET Control System is a therapeutic product designed for individuals who require specific Ultraviolet radiation therapy for the treatment of psoriasis and vitiligo."	"The Houva 3 Phototherapy System with PhotoSense II is a therapeutic product designed for individuals who require specific Ultraviolet radiation therapy for the treatment of psoriasis and vitiligo."	Identical
Software	The controller board manages the function for the applied system, but is designed to interface with multiple systems; however, the control boards use on a single unit continues to manage the functions for that applied system in an equivalent fashion	The controller board manages the function for the applied system	Equivalent
Lamp Type(s) and Wavelengths	UVA-F72T12/BL/HO (PUVA) @ 320-400 nm UVB-NB-TL100W/01 FS72 @ 311-313 nm	UVA-F72T12/BL/HO (PUVA) @ 320-400 nm UVB-BB-FSX72T12/UVB-HO @ 265-320 mn UVB-NB-TL100W/01 FS72 @ 311-313 nm	Identical
Control (Timer) Type	Digital Timer Crystal controlled	Digital Timer Crystal controlled	Identical
Electrical Safety	Devices is certified to meet current electrical safety standards	Designed and is certified to current UL and CSA standards	Identical
Compatibility with environment and	Device meets current electromagnetic	Device meets current electromagnetic	Identical

other devices	compatibility standards	compatibility standards	
Where Used	Primarily used in a clinical settings	Primarily used in clinical settings	Identical
Mechanical Safety	Physical characteristics are identical	Physical characteristics are identical	Identical
Human Factors	LCD Touch screen, user programmable options, alarms and lockouts	LCD Touch screen, user programmable options, alarms and lockouts	Identical

Summary of technological characteristics / performance data:

This modified device has the same indications for use and technological characteristics as the predicate devices. Comparisons of the following technological characteristics, and non-clinical performance data (indicated by *), were assessed, and the results demonstrate the substantial equivalence to the predicates:

Description of Testing

The safe and effective performance of the *Houva V with Houva-NET Control System* has been clearly demonstrated by bench tests:

- System Verification Section 18 A-M
- Software Validation Section 16 A-L

Performance data demonstrates continued conformance with IEC 60601-1 Ed.2

Clinical testing was not required to establish equivalency of the device.

The comparison of technological characteristics, non-clinical performance data, safety testing, and software validation, demonstrates that the device is as safe, as effective, and performs as well or better than the predicate devices.

Conclusion:

National Biological Corporation concludes that the device is substantially equivalent to the currently legally marketed predicate devices. The *Houva V with Houva -NET Control System* does not introduce new indications for use or intended use, has identical or equivalent technological characteristics, provides images of equivalent diagnostic capability, and does not introduce new potential hazards or safety risks. The device is as safe, as effective, and performs as well or better than the predicate devices.