



Food and Drug Administration  
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Silver Spring, MD 20993-0002

June 14, 2016

International Biomedical  
Ms. Amy Pieper  
Director of Regulatory Affairs  
8206 Cross Park Dr.  
Austin, Texas 78754

Re: K160238  
Trade/Device Name: Airborne Phototherapy Light  
Regulation Number: 21 CFR 880.5700  
Regulation Name: Neonatal Phototherapy Unit  
Regulatory Class: II  
Product Code: LBI  
Dated: March 30, 2016  
Received: April 27, 2016

Dear Ms. Pieper:

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 yours,

 Tina Kiang  
-S

for Erin I. Keith, M.S.  
Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K160238

Device Name

Airborne Phototherapy Light

Indications for Use (Describe)

The Airborne Phototherapy Light System is intended to be used in one of two modes: observation light mode or phototherapy light mode. The observation light mode utilizes white light and is intended to be used as auxiliary lighting that supplements the ambient lighting. The phototherapy light mode utilizes blue light and is intended to be used in the treatment of neonatal hyperbilirubinemia.

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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**K160238 510(K) SUMMARY**

**Manufacturer's Name:** International Biomedical  
8206 Cross Park Drive  
Austin, Texas 78754

**Corresponding Official:** Amy Pieper  
Director of Regulatory

**Telephone Number:** (512) 873-0033  
**Fax Number:** (512) 873-9090

**Preparation Date:** June 10, 2016

**Trade Name:** Airborne Phototherapy Light

**Common or Usual Name:** Neonatal Phototherapy Unit

**Classification Name and Number:** Unit, Neonatal Phototherapy  
21 CFR 880.5700  
Product Code: LBI

**Predicate Device:** Atom Medical – Bili-Therapy Spot Type – k103828  
 Draeger Medical Systems – NanoBlu 500 – k113206

**Device Description**

The Airborne Observation and Phototherapy Light is an LED phototherapy (and observation) light. The LED light has both white and blue LED lights that are designed to serve as an observation light or a phototherapy light for the treatment of neonatal hyperbilirubinemia, commonly known as neonatal jaundice. The phototherapy light can be used for infants in incubators by mounting it on the hood

**Intended Use**

The AirBorne Observation & Phototherapy Light System is intended to be used in one of two modes: observation light mode or phototherapy light mode. The observation light mode utilizes white light and is intended to be used as auxiliary lighting that supplements the ambient lighting. The phototherapy light mode utilizes blue light and is intended to be used in the treatment of neonatal hyperbilirubinemia

## Substantial Equivalence Discussion

	<b>Proposed Airborne Phototherapy Light</b>	<b>Predicate K103828 Bili-Therapy Spot Type</b>	<b>Predicate K113206 NanoBlu 500</b>
Indications for Use	The Airborne Observation & Phototherapy Light System is intended to be used in one of two modes: observation light mode or phototherapy light mode. The observation light mode utilizes white light and is intended to be used as auxiliary lighting that supplements the ambient lighting. The phototherapy light mode utilizes blue light and is intended to be used in the treatment of neonatal hyperbilirubinemia.	The Bili-Therapy Spot Type is a phototherapy unit intended for the treatment of neonatal hyperbilirubinemia.	The Drager NanoBlu 500 LED Phototherapy Light is intended to treat neonatal hyperbilirubinemia by providing phototherapeutic light to the body of the patient. It is intended for use on the recommendation and under the supervision of healthcare professionals. Additionally, this product can be used with an under-baby phototherapy light to increase patient coverage.
Environment for Use	Hospital or institution	Hospital or institution	Hospital or institution
Patient Population	Neonatal	Neonatal	Neonatal
Prescriptive	yes	yes	yes
Patient Connection	none	none	none
Technology	Blue light-emitting diodes (LEDs)	Blue light-emitting diodes (LEDs)	Blue light-emitting diodes (LEDs)
Wavelength	400-500 nm	Peak 450 to 475 nm	400-550 nm
Irradiation Intensity	12-27 $\mu\text{W}/\text{cm}^2/\text{nm}$	30-40 $\mu\text{W}/\text{cm}^2/\text{nm}$	Minimum 40 $\mu\text{W}/\text{cm}^2/\text{nm}$
Sound level	< 60dB	60 dB or less	Not published
Power Requirements	8.9V @ 420mA or 80-264VAC, 50-60Hz	Rated voltage 120VAC, Power consumption 30VA, frequency 50/60 Hz	90 VAC to 240 VAC Operating Voltage
Electrical Safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-50	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-50	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-50

### Discussion of Differences

The indications for use of the Airborne Phototherapy Light designate the light therapy as blue light while the predicate (K113206) refers to the “phototherapeutic light.” This addition does not raise any new questions of safety or effectiveness, since the phototherapeutic light for treatment of hyperbilirubinemia is considered within the “blue” light spectrum.

The indications for use of the Airborne Phototherapy Light states the addition of a white light mode for use as auxiliary lighting which is not in the intended use of the predicates (K103828, K113206). This addition does not raise any new questions of safety or effectiveness as this mode is for auxiliary lighting needs, not treatment of hyperbilirubinemia.

The irradiance delivered by the Airborne Phototherapy Light is slightly less than the irradiance delivered by the predicate devices; however, the effect on the patient of the irradiance delivered is within 10% of the level delivered by the predicate devices. According to the American Academy of Pediatrics Guidelines for the Treatment of Hyperbilirubinemia, irradiance levels as low as  $5 \mu\text{W}/\text{cm}^2/\text{nm}$  result in a 15% decrease of serum bilirubin in the first 24 hours of use. Therefore the while the irradiance levels for the AirBorne Phototherapy Light are slightly lower, they are within the levels required for a therapeutic effect per the American Academy of Pediatrics Guidelines for the Treatment of Hyperbilirubinemia.

The differences between the Airborne Phototherapy Light and the predicates do not raise any new questions of safety and effectiveness.

### **Performance Testing**

Testing was performed to confirm compliance to the following standards:

- IEC 60601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2, Medical Electrical Equipment, Part 1-2: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility
- IEC 60601-2-50, Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of Infant Phototherapy Equipment

The Airborne Phototherapy Light met all the performance requirements as outlined above in the standards and thus can be found to be substantially equivalent to the predicate devices.

In addition to compliance with the relevant standards, a usability risk analysis was performed indicating that all the critical tasks for the Airborne Phototherapy Light are minor in severity, thus human factors testing is not need.

### **Clinical and Non Clinical Tests**

No other clinical or nonclinical testing was performed.

### **Conclusions**

In regards to intended use and technology, the Airborne Phototherapy Light is substantially equivalent to the listed predicates in indications for use, patient population, environment for use, technical characteristics and compliance with international standards.

Any differences between the Airborne Phototherapy Light and the predicates do not raise any new questions of safety and effectiveness. Therefore, the subject device is considered substantially equivalent to the Bili-Therapy Spot Type cleared under K103828 and the Drager NanoBlu 500 LED Phototherapy Light cleared under K113206.