K103828

510(k) Summary
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11-Mar-11

MAR 29 2011

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Official Contact: Tsuyoshi Sugino – Regulatory Affairs Manager

Proprietary or Trade Name: BILI-THERAPY Spot Type

Common/Usual Name: Neonatal phototherapy unit.

Classification Name/Code: LBI – Neonatal phototherapy unit.
CFR 880.5700

Device: BILI-THERAPY Spot

Predicate Device: Respironics – Bili-Tx K070180

Device Description:
The BILI-THERAPY Spot Type is an overhead unit available in two versions:

- Arm
- Stand

The BILI-THERAPY Spot Type phototherapy unit shines a blue light onto the patient for the treatment of hyperbilirubinemia. The unit has no direct contact with the patient.

Indications for Use:
The BILI-THERAPY Spot Type is a phototherapy unit intended for the treatment of neonatal hyperbilirubinemia.

Environment of Use: Hospital or institutional

Summary of substantial equivalence

The Atom Phototherapy Units
The BILI-THERAPY Spot Type was compared to the predicate Respironics BiliTx (K070180).

Indications for Use – The BILI-THERAPY Spot Type is a phototherapy unit intended for the treatment of neonatal hyperbilirubinemia.

The BILI-THERAPY Spot Type has the same intended use (treatment of hyperbilirubinemia) as the Respironics BiliTx (K070180).

Patient Population – The BILI-THERAPY Spot Type is indicated for Neonates as is the predicate.

Environment for use – The BILI-THERAPY Spot Type has the identical environments for use as the predicate (hospital/institutional)

Prescriptive – The BILI-THERAPY Spot Type is prescriptive as is the predicate.

Design and Technology – The BILI-THERAPY Spot Type has equivalent design and features as the predicate and has the identical technology to the predicate.

Performance and Specifications – The BILI-THERAPY Spot Type has equivalent specifications of performance as the predicate.

Compliance with standards – The BILI-THERAPY Spot Type and predicate device declare compliance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-50.

Conclusion
The BILI-THERAPY Spot Type is substantially equivalent to the predicate Respironics BiliTx (K070180) in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards

Performance Testing

We have performed bench tests which included the list below and found that the BILI-THERAPY Spot Type met all pass /fail criteria, cited standards requirements and were found to be equivalent in comparison to the predicate.

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995

- IEC 60601-1-2: Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)).

- IEC 60601-2-50: 2009 Medical Electrical Equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment.

Device Comparison

	BILI-THERAPY Spot Type	Respironics Bili-Tx (K070180)
General Attributes		
Indications for Use	The BILI-THERAPY Spot Type is a phototherapy unit intended for the treatment of neonatal hyperbilirubinemia.	The Bili-Tx is intended to treat hyperbilirubinemia through phototherapy in a home or hospital/institutional environment
Patient Population	Neonatal	Neonatal
Environment of Use	Hospital or institutional	Home or hospital/institutional
Prescriptive	Yes	Yes
Patient Connection	No	No with Bili-Tx overhead Yes with Bili-Tx Fiber optic light panel
Technology	Blue light-emitting diodes (LEDs)	Blue light-emitting diodes (LEDs)
Technical specifications		
Dimensions	Arm Type: 1000W x 130D x 450H (mm) Stand Type: 450W x 710D x 1900H (mm)	Illuminator 16.10 cm x 7.40 cm (6.34 in x 2.92 in)
Weight	Arm Type: approximately 2.2 kg Stand Type: approximately 12 kg	1.3 Kg (2.86 lb)
Irradiation Intensity	30-40 $\mu W/cm^2/nm$ (measurement obtained by BiliBlanket® meter at irradiation distance of 30 cm) Change in irradiance after 6 hours +/- 10% (in effective area) Effective irradiated area 20 x 30 cm	Spectral Irradiance Level Distance — Irradiance ($\mu W/cm^2/nm$) 15 cm (6 in) — 75 $\mu W/cm^2/nm$ 30 cm (12 in) — 32 $\mu Wcm^2/nm$ 45 cm (18 in) — 10 $\mu Wcm^2/nm$ 60 cm (24 in) — 9 $\mu Wcm^2/nm$
Wavelength	Peak 450 to 475 nm	Peak between 450 nm and 485 nm
Sound level	60 dB or less	52 dB
Power Supply	Rated, Voltage 120VAC Power consumption 30VA, frequency 50/60 Hz Working voltage range 120VAC +/-10%	(Input) 100 – 240 VAC, 50/60 Hz, 1.0 A
Operating Temperature	Ambient: 10-30°C Relative Humidity 30-85% (non-condensing)	15°C to 35°C
Storage Temperature	Ambient 0-45°C Relative Humidity 0-90% (non-condensing)	-20 °C to 55 °C
Mounting Options	Arm or Stand	Overhead mounting option (standard IV pole and bracket)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Atom Medical Corporation
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

MAR 29 2011

Re: K103828
Trade/Device Name: BILI-THERAPY Spot
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: March 11, 2011
Received: March 14, 2011

Dear Mr. Dryden:

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.

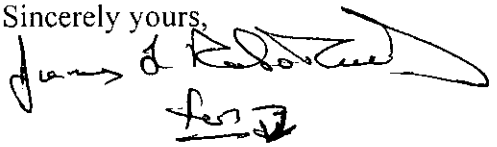
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K103828 (To be assigned)

Device Name: BILI-THERAPY Spot

Indications for Use:

The BILI-THERAPY Spot Type is a phototherapy unit intended for the treatment of neonatal hyperbilirubinemia.

Prescription Use X (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 5/29/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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