

medix

AUG 15 2011

K103735

Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the **MediLEDmini** Phototherapy Lamp.

1. Company making the submission:

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Contact:	Michael Bobadilla
E-mail:	mobobadilla@natus.com

2. Device Name:

Trade/Proprietary Name:	Unit, Neonatal Phototherapy
Common/Usual Name:	Neonatal Phototherapy Lamp
Proprietary Name:	MediLED Phototherapy Lamp
Regulation Number:	880.5700, Class II
Product Code:	LBI

3. Predicate Devices:

The **MediLEDmini** Phototherapy Lamp is substantially equivalent to the Natus Blue Light Phototherapy Unit [K022196] and the Medix MediLED Phototherapy Unit [K083179].

4. Intended Use Statement:

INDICATIONS FOR USE: The MediLED Phototherapy Lamp is intended for the treatment for neonatal hyperbilirubinemia. The device is intended for use by healthcare professionals in a clinical setting.

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5. Description of Device:

MediLEDmini is a LED Phototherapy lamp for neonatal use. It was specially crafted and designed to be used with incubators. Its small form size allows for great versatility without compromising power, since it is one of the most powerful units in the market.

LED technology is so advanced that its cold light avoids overheating in patients since it does not emit IR or UV radiation. Its high power and therapeutic efficacy reduces treatment costs, allowing the patient to be discharged in less time than with conventional phototherapy.

Its small size and versatility is very useful in small environments and where space is a priority.

The unit has 3 light intensities to choose: high-medium-low in order to answer different treatment needs

Treatment Light

Distance [cm]	Blue [$\mu\text{W}/\text{cm}^2$]	Effective Surface Length x Width [cm]
50cm	50	20 x 30

6. Testing:

The MediLED Phototherapy Lamp has been tested and meets the requirements of the following Standards:

- IEC 60601-1-2
- IEC 60601-1
- EN 60606-1-2-50

7. Rx or OTC

The MediLED Phototherapy Lamp is an Rx prescription device per 21 CFR Subpart D. The indication for use is for clinical setting only.

8. Conclusions:

The MediLED Phototherapy Lamp is substantially equivalent to the predicate device in the scope of practical application, effectiveness at this application, and ensuring the safety of its subject.

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MediLED Phototherapy Lamp does not raise any new safety or effectiveness issues.

Medix, I.C.S.A.

Eng. Juan Carlos Guerra
Vice President

Date: _____

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Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Medix I.C.S.A.
C/O Mr. James H. Knauss
Contract Consultant
Delphi Consulting Group
11874 South Evelyn Circle
Houston, Texas 77071 - 3404

AUG 15 2011

Re: K103735
Trade/Device Name: MediLEDmini Phototherapy Lamp
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: July 27, 2011
Received: August 1, 2011

Dear Mr. Knauss:

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.

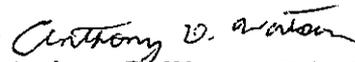
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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: K103735

Device Name: MediLEDmini Phototherapy Lamp

Indications for Use: The Medix MediLEDmini Phototherapy Lamp is intended for the treatment of neonatal hyperbilirubinemia. The device can be used with infants in a bassinet, incubator, open bed or radiant warmer. It emits a narrow band of blue light considered to be the most effective in the degradation of bilirubin.

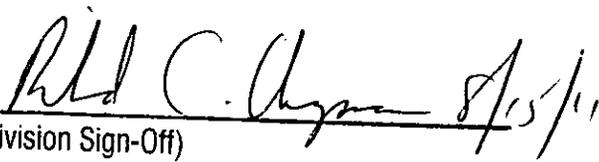
Prescription Use **YES**
(Part 21 CFR 801 Subpart D)

AND/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)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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