K083179

FEB 27 2009

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 MediLED Phototherapy Lamp.

1. Company making the submission:

Name:	**Medix I.C.S.A.**
Address:	**Jose Arias 293, Villa Lynch, San Martin** **Buenos Aires, 1672 Argentina**
Telephone:	**+54-11 4754 5555**
Fax:	**+54-11 4754 1713**
Contact:	**Analia Gaidimauskas**
E-mail:	**agaidimauskas@medix.com.ar**
U.S. Agent:	Delphi Consulting Group
Address:	11874 South Evelyn Circle Houston, Texas 77071-3404
Telephone:	713-723-4080
Fax:	713-723-0786
Contact:	J. Harvey Knauss
E-mail:	harvey.knauss@gmail.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 MediLED Phototherapy Lamp is substantially equivalent to the Natus Blue Light Phototherapy Unit [K022196].

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.

5. Description of Device:

The Medix MediLED is neonatal phototherapy equipment with blue and white LEDs, incorporating height and angle adjustments. The device is labeled and indicated for: treatment for neonatal hyperbilirubinemia. The device is intended for use in healthcare professionals in a clinical setting.

Fitted with a rolling base with brakes, column, and mobile head containing the equipment's electronics. The design allows the equipment to be used with incubators, infant warmers or cradles of all type and brand.

Features:

- Microprocessor mobile phototherapy equipment. (mobile stand with brakes)
- Ideal for use in incubators, cribs and infant warmers
- High brightness LED technology: led quantity 492 Blues ,108 whites.
- Total Hour meter (LED useful life) and partial time (treatment).
- Technical Service Indicator.
- Examination light.
- It is possible to maneuver with all LEDs on.
- Continuous height shift by means of an actuator
- Headlight positioning without the use of a tool

Commands are found on the front of the equipment's head, consisting of three keys, two of which allow to operate separately blue from white LEDs, making it possible to check the patient's real skin color or perform interventions under white light. By turning on the blue LEDs, total and treatment counters are enabled. These indicate the total and treatment time of the phototherapy unit. The third key (reset) is used to restore the treatment counter. It also has two indicators; a green one showing the equipment is connected to the power supply and ready to be used, and a yellow one indicating the need of technical service assistance.

Blue LEDs do not emit significant ultraviolet (UV) neither infrared (IR) energy, resulting in no risk of UV, IR exposure nor excessive warming up for the patient.

Treatment Light

Distance [cm]	White + Blue [uW/cm2/nm]	Blue [uW/cm2/nm]	White [uW/cm2/nm]	Effective Surface Length x Width [cm]
30cm	49	44	5	37x19
40cm	40	36	4	40x21
50cm	33	30	3	46x24

Examination light

Distance [cm]	Illuminance [Lux]	Light area Length x Width [cm]
30	3600	32x21
40	2600	
50	2000	

6. Summary of the technological characteristics of the device compared to predicate devices:

The difference from the predicate device is the method of application, the predicate device is under baby phototherapy. The MediLED Phototherapy Lamp is overhead phototherapy.

The predicate device is labeled for Home use, the MediLED Phototherapy Lamp is not.

The basic method of construction and materials is very similar. The methods of operation and indications for use are the same.

7. 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

8. 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.

9. 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.

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

Medix, I.C.S.A.

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Eng. Juan Carlos Guerra
Vice President & CEO

Date: _____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medix I.C.S.A.
C/o Mr. J. Harvey Knauss
Delphi Consulting Group
11874 South Evelyn Circle
Houston, Texas 77071

FEB 27 2009

Re: K083179
Trade/Device Name: MediLED Phototherapy Lamp
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: February 11, 2009
Received: February 13, 2009

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting 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 _____

Device Name: MediLED Phototherapy Lamp

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.

Prescription Use **YES** AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (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

510(k) Number: K053179