K071828

## 5. 510(K) Summary

GE Healthcare
General Electric Company
8880 Gorman Road, Laurel, MD 20723

AUG - 6 2007

**Section A**

1. Submitter: Ohmeda Medical, a division of GE Healthcare
   8880 Gorman Road, Laurel, MD 20723

   Contact Person: Thalia Brine
   Global Regulatory Leader
   Telephone: 410-888-5257
   Fax: 410-888-0544

   Date Prepared: 29 June 2007

2. Device Name:

   Trade Name: Lullaby™ Phototherapy System

   Common Name: Phototherapy device

   Classification Name: Neonatal Phototherapy Unit
   21 CFR 880.5700

   Product Code: LBI

3. Marketed Device: Phoenix Neonatal Phototherapy Unit CFL 101
   #K040853

4. Device Description: The Lullaby™ Phototherapy System is intended for the treatment of neonatal hyperbilirubinemia, commonly known as neonatal jaundice. This device consists of a freestanding lamp that delivers specific wavelength light to the patient positioned below the lamp.

5. Indications for Use: The Lullaby™ Phototherapy System is intended for the treatment of neonatal hyperbilirubinemia, commonly known as neonatal jaundice.

6. Comparison with Predicate Device: The Lullaby™ Phototherapy System has the same intended use as the listed predicate device, the Phoenix Neonatal Phototherapy Unit CFL 101, and the mode of action for neonatal jaundice treatment is the same between the two devices. Details of the similarities and differences between the two devices may be found in Section #11.

**Section B**

1. Non-clinical Tests: The device has been evaluated for electrical safety and output, and has been found to conform to applicable medical device safety standards.

2. Clinical Tests: None required.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient treatment. Phototherapy treatment for neonatal jaundice has accumulated a long history of safe and effective use. Additionally the design and development process of the manufacturer conforms to 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems, and the device conforms to applicable medical device safety standards, compliance verified through independent evaluation with ongoing factory surveillance. Therefore, it is the opinion of GE Healthcare that the Lullaby™ Phototherapy System is substantially equivalent with respect to safety and effectiveness to other phototherapy devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2007

Ms. Thalia Brine
Global Regulatory Leader
GE Healthcare Clinical Systems
8880 Gorman Road
Laurel, Maryland 20723

Re: K071828
Trade/Device Name: Lullaby™ Phototherapy System
Regulation Number: 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: June 29, 2007
Received: July 3, 2007

Dear Ms. Brine:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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

510(k) Number (if known): #K071828

Device Name: Lullaby ™ Phototherapy System

Indications For Use:

The Lullaby™ Phototherapy System is intended for the treatment of neonatal hyperbilirubinemia, commonly known as neonatal jaundice. This device is intended for professional use only by trained clinicians.

Prescription Use ___X___ (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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K071828