

NOV - 9 1999

K993712

Ohmeda Medical BiliBlanket Plus High Output

510(k) Summary

Submitter Information

Alberto F. Profumo, RAC (also contact person)
9065 Guilford Road
Columbia, MD 21046-1801
Tel. (410) 381- 4004
Summary prepared on November 2, 1999

Device Name(s)

Classification Names:

- Neonatal Phototherapy Unit
- AC- powered Transilluminator

Common Names:

- Phototherapy Lamp
- Transilluminator

Proprietary Name:

- BiliBlanket Plus High Output Phototherapy System

Predicate Device Information

The BiliBlanket Plus High Output Phototherapy System is substantially equivalent to the following, legally marketed products:

- Ohmeda – BiliBlanket Plus (original)
- PEP – Ultra BiliLight
- Medela - BiliBed

Indications for Use

The BiliBlanket Plus High Output Phototherapy System provides light therapy for the treatment of hyperbilirubinemia, commonly know as neonatal jaundice, during the newborn period in the hospital or home setting. In addition, the device has an optional fiberoptic cable attachment for use in transillumination of the neonate.

Product Description

The BiliBlanket Plus High Output Phototherapy System has two modes of operation:

- a) phototherapy, used for the treatment of hyperbilirubinemia; and
- b) transillumination, used for a variety of medical procedures such as locating venipuncture sites and detecting pneumothoraces or hydrocephalus.

In the phototherapy mode, a fiberoptic cable and blanket are attached to the illuminator box. Phototherapeutic light, which is light in the blue region (400 – 550 nm), is transmitted from the illuminator to the blanket via the fiberoptic cable. The blanket is applied to the patient so as to maximize the patient contact with the blanket.

The second mode is transillumination. A fiberoptic cable is attached to the illuminator, and the visible light spectrum (white light) appears at the tip of this fiberoptic cable. This lighted cable is used for facilitating vascular stick or injections; it is also used for finding pneumothoraces. Transilluminators have been used, and are being used, in NICUs and nurseries all over the world. Their intended use and user familiarity are well established.

Performance Data

Since treatment of neonatal hyperbilirubinemia with phototherapy is a well established clinical practice, Ohmeda submits that clinical or animal testing to demonstrate safety and effectiveness is not necessary. The product was subject to extensive bench testing, and, to the best of Ohmeda Medical's knowledge, the requirements of 21 CFR 820, Subpart C -- Design Controls -- were satisfied.

Assessment of Technological Characteristics

The technological characteristics of the BiliBlanket Plus High Output Phototherapy System are similar to those of the predicate devices and do not raise new safety or effectiveness issues.

Sterilization Information

The BiliBlanket Plus High output Phototherapy System is not intended to be sterilized. Cleaning and disinfecting instructions can be found in the Operation and Maintenance Manual.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Alberto F. Profumo, R.A.C.
Director, Product Assurance
Ohmeda Medical
9065 Guilford Road
Columbia, MD 21046-1801

Re: K993712
Trade Name: Ohmeda Medical-BiliBlanket Plus High Output
Phototherapy System
Regulatory Class: II
Product Code: FMZ
Dated: November 2, 1999
Received: November 3, 1999

Dear Mr. Profumo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

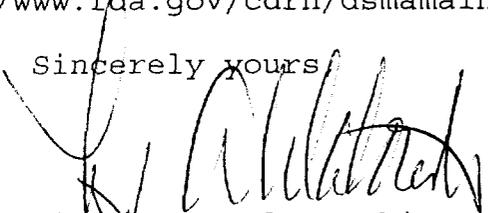
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993712

Device Name: **BiliBlanket Plus High Output Phototherapy System**

Indications For Use:

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use OR Over- The Counter Use
 (Per 21 CFR 801.109)

Salvatore Cucinotta (Optional Format 1-2-96)
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
 510(k) Number K993712