K093618

510(k) Summary (21 CFR 807.92) – restated and updated:

Submitter's Demographics:

Owner: Physician Engineered Products, Inc.
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Date of Summary preparation: November 2, 2009

APR 2 8 2010

Name of the Device:

Trade Name:	Bili-Mirror
Common Name:	phototherapy device mirror
Classification Number:	878.4370
Classification Name:	Surgical Drape and Drape Accessories
Regulatory Class:	II
Product Code:	MMP

Substantial Equivalence to Predicate Device:

510(k) #:	K043234
Trade/Device Name:	Light Drape (by Natus)
Classification Number:	878.4370
Classification Name:	Surgical Drape and Drape Accessories
Regulatory Class:	II
Product Code:	MMP
Dated:	April 5, 2005

Description of Device

The Bili-Mirror was developed under a patent licensing agreement with Stanford University – see attachments.

The Bili-Mirror serves as an enhancement to several existing phototherapy devices in the US market – such as the Natus neoBlue or the Olympic BILI-LITE that treat neonatal hyperbilirubinemia (jaundice) with bright blue-range light. The Bili-Mirror is simply a 10"-high by 54"-wide metalized, 3 mil polyester film that removably attaches (like a skirt) to the lower edge of overhead phototherapy devices. It serves three useful purposes.

1. First, the 3 ohm metalized film serves as a mirror to reflect phototherapy light from the overhead device back onto baby – thereby increasing the phototherapy dose by up to 70% - depending upon the distance of light-to-baby. (See attached data sheet.) Overhead lights provide light doses ranging from 15 to 30 μWatts/cm²/nm. By increasing the light dose by up to 70%, the result is light doses are often over 30 μWatts/cm²/nm. Other phototherapy devices in the US market, such as PEP's Ultra Bili Light, provide light doses over 60 μWatts/cm²/nm, so the increased dose for overhead devices with a Bili-Mirror attached is well within the accepted and safe range of light dosing.
2. Second, the Bili-Mirror decreases by over 95% the bright blue light "scatter" from the phototherapy device from reaching the eyes of caregivers.

3. Third, unlike the predicate device, the 3 ohm metalizing of the Bili-Mirror provides for a see-through mirror that allows good visibility of baby as viewed through the Bili-Mirror. Thus, during the delivery of phototherapy, the baby is not hidden from view.

To secure the Bili-Mirror to a phototherapy device, all along the inside top edge of the film sheet, 1/8" from the top, is attached a ½" wide 3M double-sided adhesive strip with a peel-off cover paper. This adhesive strip: a) adheres well to the metal or plastic housings of various phototherapy devices, b) releases well from the phototherapy device without leaving adhesive residue, and c) does not mar the surface of the phototherapy device.

To install the Bili-Mirror onto an overhead neonatal phototherapy device, the peel-off cover is removed from the adhesive strip which is then pressed onto the lower, outer edge of the device housing. Depending upon the phototherapy device being used, the 54"-long Bili-Mirror will wrap around most of the perimeter of the device housing – leaving a gap of at least 5" at the back. This gap prevents thermal trapping inside the "skirt" created by the wrap-around Bili-Mirror situated below the light source.

The overhead phototherapy device is then positioned over the baby bassinette so as to leave at least 1" between the bottom of the Bili-Mirror and the top of the bassinette. This positioning: a) prevents the Bili-Mirror from coming into direct contact with baby, and b) provides for air circulation into and out of the bassinette.

Intended Use –

Bili-Mirrors are intended to attach to overhead phototherapy light fixtures to limit the scattering of light.

Technological Characteristics

There are only 2 components that comprise the Bili-Mirror: metalized polyester film and an adhesive strip. Their technological characteristics are as follows:

Film:

Material:	clear polyester plastic metalized to 3 ohms - provides: reflectance of 95% of blue light transmission of 5% of blue light
Dimensions:	10" high x 54" long x 3mil thick
Serated:	at 18" intervals to allow convenient folding and packaging

Adhesive strip:

Material:	3M Model 476XL - ½" wide double-sided adhesive strip adhesed 1/8" from the top edge along the entire 54" length of film with peel-off paper to expose the adhesive surface for reversibly bonding to an overhead phototherapy device

Summary of Non-Clinical and Clinical testing:

i) 3 mil thick polyester film metalized to 3 ohms tested for:
- reflection of blue phototherapy light;
- see-through capability;
- resistance to scratching

- no residue from use

ii) 3M 476XL adhesive strip tested for:
- Adhesion
- Release after use
- Effect on phototherapy device surface

iii) Bili-Mirror tested on two commonly-used overhead infant phototherapy devices: Olympic Bili-Lite and Natus neoBlue for:
- Light dose at baby area;
- Temperature change at baby area;
- Light transmission through Bili-Mirror;
- Subjective visibility of baby through Bili-Mirror
- Distance to baby

Discussion of Clinical Testing:

Enclosed please find test results that determined:

1) the light dose effect onto baby with or without the Bili-Mirror;
2) the temperature effect on baby's immediate environment with or without the Bili-Mirror;
3) the distance of the Bili-Mirror to baby under operating conditions;
4) blue light transmission through and inside reflectance from the Bili-Mirror;
5) subjective visibility of baby through the Bili-Mirror with the phototherapy lights on.

To summarize,

1) the light dose from two commonly-used phototherapy devices alone ranged from 21.9 to 27.4 μWatts/cm²/nm – less than the recommended 30+ μWatts/cm²/nm. With the addition of the Bili-Mirror, the light doses rose to the 30.7 to 32.5 μWatts/cm²/nm range – within the recommended dose range. Light doses were not increased to dangerous levels which may exist over 100 μWatts/cm²/nm.
2) the temperature around baby rose from the two commonly-used phototherapy devices alone by 1.5 to 2.9°C – within the desirable temperature range for unclad babies. With the addition of the Bili-Mirror, the temperature rose another 0.1 to 0.7°C – still well within the desirable range and well below the upper limit normally provided in a hospital setting.
3) depending upon the phototherapy device being used, the Bili-Mirror edge remains at least 2 inches from the maximum reach of a baby in a bassinette – therefore not in contact with the baby;
4) the normal scatter of light from an overhead phototherapy device is reduced by 95% in the area covered by the Bili-Mirror;
5) visibility of the baby through the Bili-Mirror is deemed to be good.

Conclusions from Testing:

1) Use of the Bili-Mirror predictably raises the light dose onto baby – often to a more desirable dose – but not to a dangerous level;
2) Use of the Bili-Mirror predictably raises the temperature of the immediate environment of the baby by a relatively small amount – within the desirable range – but not to a dangerous level;

3) The Bili-Mirror does not come in contact with baby during use; therefore does not require additional biocompatibility testing;
4) Use of the Bili-Mirror effectively limits the scatter of light from the phototherapy device;
5) The visibility of baby by the caregiver through the Bili-Mirror may provide improved safety over an opaque device

Additional Conclusions:

1) The following data demonstrate Substantial Equivalence to the predicate device:
   a) Both the Bili-Mirror and the Light Drape are constructed of flexible materials that removably attach to the lower edge of an overhead infant phototherapy device;
   b) Both the Bili-Mirror and the Light Drape span 9 to 10 inches below the lower edge of the overhead infant phototherapy device and surround or nearly surround the lower perimeter of the device;
   c) Both the Bili-Mirror and the Light Drape, when properly positioned, do not come in contact with the baby undergoing phototherapy;
   d) **Both the Bili-Mirror and the Light Drape limit the scattering of light from the phototherapy device by 95% or more over the surface area covered by both devices.**

2) The following data areas do not contribute to a determination of Substantial Equivalence to the predicate device because there is no published data for the predicate device with which to compare:
   a) the effect of the device upon the light dose on baby,
   b) the effect of the device upon the temperature around baby, or
   c) the effect of the device upon the visibility of baby.

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

APR 2 3 2010

Robert Rose, MD
Chief Executive Officer
Physician Engineered Products, Incorporated
103 Smith Street
Fryeburg, Maine 04037

Re: K093618
Trade/Device Name: Bili-Mirror (Accessory to Neonatal Phototherapy Light)
Regulation Number: 21CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: MMP
Dated: April 2, 2010
Received: April 6, 2010

Dear Dr. Rose:

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,

for Anthony 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

510(k) Number (if known): K093618

Device Name: Bili-Mirror (Accessory to Neonatal Phototherapy Light)

Indications For Use:

Bili-Mirrors are intended to attach to overhead phototherapy light fixtures to limit the scattering of light.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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: K093618