K971601

SEP 24 1997

Attachment C

SAFETY AND EFFECTIVENESS SUMMARY

SAFETY AND EFFECTIVENESS SUMMARY

*This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Olympic Medical
5900 First Ave. S.
Seattle, WA 98108
206-767-3500

Contact Person: Joseph Stefanile

Common or usual name of device ---------- Phototherapy Light
Trade or proprietary name ---------- Olympic Bili-Bassinet
Classification name (if known) ---------- 80 LBI Unit, Neonatal Phototherapy
Predicate device(s) to which substantial equivalence is being claimed ---------- Olympic Bili-Lite and Ohmeda Bili-Blanket

Device Description

1. Brief explanation of how the device functions.

   The Olympic Bili-Bassinet has three phototherapy fixtures built into a bassinet.

   The two identical overhead fixtures swing and lock in their up position. They are mounted on counter-balanced arms. Thier storage position is recessed into the sides of the bassinet.

   The phototherapy pad is a pad/mattress, which is transparent to light. Unlike a fiberoptic pad, which used plastic optical fibers within the pad to transmit the light from the remote light box, the Bili-Bassinet light box is below the pad/mattress and shines through the pad.

   All fixtures use conventional blue (type "B") fluorescent phototherapy lamps. "Daylight" and high-intensity (type BB) fluorescent lights are available for use in the overhead fixtures.

2. Basic scientific concepts that form the basis for the device.

   The Bili-Bassinet is a very simple device utilizing conventional fluorescent lamp technology. The overhead lamps are conventional air cooled and the light pad is fan cooled.

3. Significant physical and performance characteristics of the device. (Eg. device design and physical properties.

Physical:

Height	53.5"
Length	39.5"
Width	32.0"
Weight	220 lbs

Electrical:

3A at 115/120 Vac

Total wattage = 360 W

Lamp Type:

Fluorescent

Maximum Irradiance: μw/cm²/nm

Overhead	9	using "Daylight" bulbs
	18	using "B" bulbs
	18	using "BB" bulbs
Pad	30	on Low setting
	50	on HI setting

4. Intended Use of the device

A. The diseases or conditions the device will diagnose, treat, prevent, cure, or mitigate.

Neonatal Hyperbilirubinemia

B. The patient population for which the device is intended.

Infants

5. Does the indication statement (4) differ from those of the predicate device?

Check one: ____ Differs (complete section 6)
X Does not differ (skip to section 7)

6. Explanation of why the differences are not critical to the intended use of the device and why the differences do not affect the safety or effectiveness of the device.

N/A

7. The technological characteristics of the device to the predicate product.

(See comparison chart next page)

Comparison Chart

	New Device	Predicate Devices		
Manufacturer	**Olympic**	**Olympic**	**Ohmeda**	
Model	Bili-Bassinet 581	Bili-Lite Model 33	Bili-Blanket 6600-0104-960	
Physical: Height Length Width Weight	 53.5" 39.5" 32.0" 220 lbs	 62.5" 25.0" 24.5" 67 lbs	 10.5" 11.0" 4.5" 14 lbs	
Electrical Req. Lamp Wattage Total Wattage	3A at 115/120 Vac 2 x 80 W overhead 120 W P.T. Pad 360 W	2A at 115/120 Vac 270 W	2A at 100/120 Vac 140 W 250 W	
Lamp Type	Fluorescent	Fluorescent	Quartz Halogen	
Lamp Life	9000 Hours	9000 Hours	300 Hours	
Leakage current	Less than 100 Microamperes	Less than 100 Microamperes	Less than 100 Microamperes	
Ground Impedance	Less than 0.1 ohm	Less than 0.1 ohm	Less than 0.1 ohm	
Max. Irradiance ($\mu w/cm^2/nm$)	9 "Daylight" Bulbs 18 "B" Bulbs 40 "BB" Bulbs P.T. Pad 30 Low 50 Hi	9 Daylight" Bulbs ① 20 "B" Bulbs ① 40 "BB" Bulbs ①	 P.T. Pad 18 - Low 30 - Med 42 - HI	
Controls & Indicators	• On/Off Switches (1 ea. for overhead) • HI/OFF/LOW for P.T. Pad	• On/Off Power Switch	• On/Off Power Switch • Illuminated Power Indicator	
Standards	UL-544 CSA/NRTL IEC 601-1	UL-544 CSA/NRTL	UL-544 IEC 601-1	
Accessories	P.T. Pad Cover (disposable)	Tilt Accessory Bili-Timer	P.T. Pad Cover (2 types-disposable)	
Intended Use	For the treatment of Neonatal Hyperbilirubinemia	For the treatment of Neonatal Hyperbilirubinemia	For the treatment of Neonatal Hyperbilirubinemia	

① At 15 inches

8. A brief description of nonclinical tests and their results.

Test		Result
Light Output (μw/cm²/nm)	----	See Comparison Chart for light output
Electrical Safety Tests	----	Meets applicable standards including ground impedance of less than 0.1 ohm and leakage current of less than 100 microamperes.
Tip-over Safety Test	----	Meets or exceeds 10° stability (CSA Standard)
Tripartite Biocompatibility	----	Meets guidance document requirements.
Temperature Tests	----	Meets applicable standards.
Safety Side Latch Strength Test	----	Meets 25kg inward and outward force test requirement.
Weight Capacity Test	----	Passes 4 times capacity tests
Fluid Spill Test	----	Passed.
Over Temperature Thermostat Safety Test	----	Thermostat performance verified.

9. A brief description of clinical tests submitted, referenced or relied on for 510(k) clearance.

N/A

10. Conclusions drawn from nonclinical and clinical tests that demonstrate the device is safe, effective, and performs as well as or better than the legally marketed device.

    1. Performance is equal to predicate devices.

    2. Device safety is verified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Joseph P. Stefanile
Product Development Manager
Olympic Medical Corporation
5900 First Avenue, South
Seattle, Washington 98108

SEP 24 1997

Re: K971601
Trade Name: Olympic Bili-Bassinet
Regulatory Class: II
Product Code: LBI
Dated: June 24, 1997
Received: June 27, 1997

Dear Mr. Stefanile:

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 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) 594-4618. 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): K971601

Device Name: Olympic Bili-Bassinet

Indications For Use:

For the treatment of Neonatal Hyperbilirubinemia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Vern Nakamura for PXC

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number

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