MAY 17

K991627

## 510(k) SUMMARY

(As required by 21 CFR 807.93)

A 510(K) Summary for the Wallaby 3 Phototherapy System™ is listed below. A separate copy of the summary on Respironics letterhead is also included in Appendix A2 at the end of this section.

**Establishment Registration Number:** 1040777

**Submitter:**
Betsy Cortelloni
Respironics Georgia, Inc.
1255 Kennestone Circle
Marietta, GA 30066
Phone: 770-429-2894
Fax: 770-499-1418

**Date Prepared:** 07-May-1999

**Name of Contact:** Betsy Cortelloni, Regulatory Affairs Manager

**Device Name:** Wallaby 3 Phototherapy System™

**Device Model Number:** 3600

**Classification Name:** Neonatal Phototherapy, 21 CFR 880.5700

**Device Classification:** LBI

**Predicate Devices:** Fiberoptic Medical Products, Inc., Wallaby II cleared under K883779 (11/14/1988)

**Device Description:** The Wallaby 3 Phototherapy System is a medical device that provides therapeutic light through a fiberoptic cable bundle and panel for the treatment of neonatal jaundice (hyperbilirubinemia). The Wallaby 3 Phototherapy Illuminator, which is a replacement product for the Wallaby II, will work with existing Wallaby phototherapy panels. The Wallaby 3 illuminator operates on both domestic and international voltages (120VAC/230VAC, 50/60 Hz).

(510(k) summary con't)

**Intended Use:**

The Wallaby 3 is intended to treat hyperbilirubinemia through phototherapy in a home or hospital environment. Some conditions which may require treatment include (but not exclusive to) are:

- Prematurity
- Liver Dysfunction
- ABO Incompatibility
- Diabetes in Mother
- Certain drugs

**Comparison of Technological Characteristics:**

The Wallaby 3 phototherapy illuminator is an improvement over its predecessor, Wallaby II. Both devices provide therapeutic light delivered from an MR16 type, 150 watt, tungsten-halogen bulb through fiberoptic cable. The existing fiberoptic cable and panel (available in two sizes) has not changed as a result of the new device.

The light intensity settings will be identical to the Wallaby II illuminator. The device will provide for two user selectable intensity levels. The two selectable levels shall be 25 $\mu W/cm^2/nm$ and 35 $\mu W/cm^2/nm$ for the smaller phototherapy panel (Model EG2000N) and 10 $\mu W/cm^2/nm$ and 15 $\mu W/cm^2/nm$ for the larger phototherapy panel (Model EG2000). The selection method shall be discrete and not continuously variable. The selector switch label has been revised from "Irradiance Level" to "Light Level" in order to clarify the function to the user.

Both devices have an optical filter to block any UV or near-IR radiation outside the 400–550 nm range that is emitted by the light source to avoid damaging the eyes and the skin.

Both devices have a redundant lamp system to ensure that the patient receives therapy with minimum interruption. The Wallaby II requires that the user push

(510(k) summary con't)

a manual button to move the back-up lamp into position once the primary lamp has failed. However, the Wallaby 3 has an automatic lamp redundancy system. This system automatically senses a lamp failure and moves the new lamp into position immediately. No action is required by the user to initiate this action.

Both devices have a safety feature to prevent the user from looking directly at the light source when the panel is detached. None of our competitor's illuminators have this feature.

**Non-Clinical Testing:** The Wallaby 3 Phototherapy Illuminator has been tested and complies with the following standards:

- CSA–22.2 No. 601-1M90
- UL 2601-1
- EN60601-1
- EN60601-2

**Conclusion:** The Wallaby 3 Phototherapy System has the same intended use and functionality as the predicate Wallaby II. The data supports that Wallaby 3 is substantially equivalent to the Wallaby II.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 1999

Ms. Betsy Cortelloni
Regulatory Affairs Manager
Respironics® Georgia, Incorporated
1255 Kennestone Circle
Marietta, Georgia 30066-6029

Re: K991627
Trade Name: Wallaby 3 Phototherapy System™, Model 3600
Regulatory Class: II
Product Code: LBI
Dated: May 10, 1999
Received: May 11, 1999

Dear Ms. Cortelloni:

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 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

**Center of Devices and Radiological Health**



**510(k) Number (if known):** K991627

**Device Name:** WALLABY 3 PHOTOTHERAPY SYSTEM

**Indications for Use:**

The Wallaby 3 is intended to treat hyperbilirubinemia through phototherapy in a home or hospital environment.

(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)

Rebecca Cucinotta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991627

PRESCRIPTION DEVICE