K021531

MAY 31 2002

510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA and21CFR § 807.92

I. NAME OF SUBMITTER

RPI
Replacement Parts Industries, Inc.
P.O. Box 5019
Chatsworth, California
91313-5019

Phone Number: (818) 882-8611

Contact Person:
Ira Lapides, President/CEO

Date Prepared: May 6, 2002

II. DEVICE NAME AND CLASSIFICATION

Proprietary Name:	RPI Replacement phototherapy lights
Common or Usual Name:	Replacement phototherapy lights
Classification:	Class II, 21 CFR 880.5700, Unit, Neonatal Phototherapy LBI

III. PREDICATE DEVICES

The RPI replacement phototherapy lights are substantially equivalent in design and indications for use to the following devices currently in commercial distribution:

- Infant Intensive Care System, Free-Standing Infant Warmer, Air-Shields Inc., Hatboro, PA 19040; K875270
- Phototherapy System PTM78, Air-Shields, Inc., Hatboro, PA 19040; K840454
- Duo-Light Phototherapy Unit, Air-Shields, Inc., Hatboro, PA 19040; K971256
- Resuscitaire Radiant Warmer, Hill-Rom Air-Shields, Hatboro, PA 19040; K003335 and K940951

IV. DESCRIPTION

The RPI Replacement phototherapy lights are intended to be used as replacement parts for various Hill-Rom Air Shields phototherapy units and infant radiant warmers.

The replacement phototherapy lights are available in different wattage and other specifications. The lights are provided nonsterile.

V. INTENDED USE

RPI replacement phototherapy lights are designed to be used as replacement light lights for use with various phototherapy units and infant radiant warmers

VI. TECHNOLOGICAL CHARACTERISTICS

No new technology, materials, or change in efficacy have been introduced by RPI in the manufacture of the RPI Replacement phototherapy bulbs. The design, form, and materials of the lights are identical to their predicate devices. All devices are provided nonsterile to the user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2002

Mr. Ira Lapides
President
Replacement Parts Industries, Incorporated
P. O. Box 5019
Chatsworth, California 91315-5019

Re: K021531
Trade/Device Name: RPI Replacement Phototherapy Bulbs
Regulation Number: 880.5700 and 880.5130
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI and FMT
Dated: May 8, 2002
Received: May 10,2002

Dear Mr. Lapides:

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.

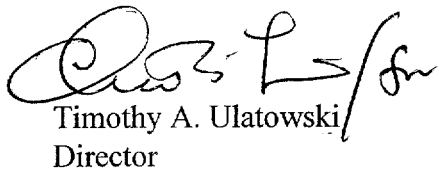
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/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

INDICATIONS FOR USE

Applicant: Replacement Parts Industries, Inc. (RPI, Inc.)

510(k) Number (if known): N/A* K021531

Device Name: RPI Replacement phototherapy bulbs

Indications For Use:

RPI replacement phototherapy bulbs are designed to be used as replacement light bulbs for use wi various phototherapy units and infant radiant warmers.

(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 _____
Per 21 CFR 801.109

Patricia Cascante

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021531