K020966

JUN 1 3 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: March 19, 2002

II. DEVICE NAME AND CLASSIFICATION

Proprietary Name:	RPI Replacement Heating Elements
Common or Usual Name:	Replacement Heating Elements
Classification:	Class II, 21 CFR 880.5130, Infant Radiant Warmers FMT

III. PREDICATE DEVICES

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

- RPI Models AIH039 and AIH100: Infant Care System, Narco Air-Shields; K790137
- RPI Models AIH040 and AIH094: Infant Intensive Care System, Free-Standing Infant Warmer, Air-Shields Inc., Hatboro, PA 19040; K875270
- RPI Model AIH097: Resuscitaire Radiant Warmer, Hill-Rom Air-Shields, Hatboro, PA 19040; K003355 and K940951
- RPI Model AIH099: Stabilet Infant Radiant Warmer, Hill-Rom, Inc. Batesville, IN 47006; K94904
- RPI Model AIH098: Stabilet Infant Radiant Warmer, Hill-Rom, Inc., Batesville, TN 47006; K913945

IV. DESCRIPTION

The RPI Replacement Heating Elements are intended to be used as replacement parts for the Hill-Rom Air Shields infant radiant warmers. The RPI heating elements are used to emit infrared radiant heat in an infant radiant warmer to maintain an infant's body temperature.

The Replacement Heating Elements are available in different outputs (wattage) and terminations. The heating elements are provided nonsterile.

V. INTENDED USE

The RPI heating elements are used to emit infrared radiant heat in an infant radiant warmer to maintain an infant's body temperature. The heating elements are identical to those supplied as original equipment as part of the infant radiant warmer.

VI. TECHNOLOGICAL CHARACTERISTICS

No new technology, materials, or change in efficacy have been introduced by RPI in the manufacture of the RPI Replacement Heating Elements. The design, form, and materials of the probes 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

JUN 13 2002

Mr. Ira Lapides
President
Replacement Parts Industries, Incorporated
P.O. Box 5019
Chatsworth, California 91313-5019

Re: K020966
Trade/Device Name: RPI Replacement Heating Elements
Regulation Number: 880.5130
Regulation Name: Infant Radiant Warmer Accessory
Regulatory Class: II
Product Code: FMT
Dated: March 21, 2002
Received: March 25, 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,

Susan Runner

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

Enclosure

Include the following "Indications For Use" page that contains the applicant's name, name of the device and the intended use of the device. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the "indications for use" statement.
*For a new submission, do NOT fill in the 510(k) number blank.

INDICATIONS FOR USE

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

510(k) Number (if known): N/A* K020966

Device Name: RPI Replacement Heating Elements

Indications For Use:

The RPI heating elements are used to emit infrared radiant heat in an infant radiant warmer to maintain an infant's body temperature. The heating elements are identical to those supplied as original equipment as part of the infant radiant warmer.

(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 Cuccinotta
(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K020966