

FEB 26 1998

DeRoyal Industries, Inc.  
Infant Transport Mattress

2980009

510(k) Summary

**SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION  
UPON WHICH  
AN EQUIVALENCE DETERMINATION COULD BE BASED**

**SUBMITTER INFORMATION**

NAME:	DeRoyal Industries, Inc.	TELEPHONE:	(423) 938-7828
ADDRESS:	200 DeBusk Lane	CONTACT:	Camille Matlock
	Powell, TN 37849	DATE OF PREPARATION:	February 9, 1998

**DEVICE NAMES**

NAME:	DeRoyal Industries, Inc. Infant Transport Mattress
COMMON/USUAL NAME:	Infant Transport Mattress
CLASSIFICATION NAME (if known):	Pack, Hot, Chemical

**PREDICATE OR LEGALLY MARKETED DEVICES**

Prism Technologies

**DEVICE DESCRIPTION**

The DeRoyal Industries, Inc. Infant Transport Mattress is a device intended for medical purposes to provide warm therapy that helps maintain infant body temperature.

Device Design/Materials Used/Physical Properties: The DeRoyal Infant Transport Mattress is designed similar to those marketed by other manufacturers. The pouch is comprised of a low-density polyethylene (LDPE) film bag which contains the activation ingredient, sodium acetate (food grade).

**DEVICE INTENDED USE**

The DeRoyal Industries, Inc. Infant Transport Mattress is indicated for use to assist in maintaining infant body temperature.

**TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICE(S)**

Characteristic	DeRoyal Device	Other Devices
Pouch Dimension	Approximately 16" X 9.5"	Approximately 13" X 9"
Pouch Material	LDPE	LDPE or Other Similar Material
Active Ingredient	Sodium Acetate (Food Grade)	Sodium Acetate (Food Grade)
Trigger	Internally Located	Internally Located
Sterility	Non-Sterile	Non-Sterile
Approximate Temperature Achieved at Activation	105° F	104° F



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Camille Matlock  
Regulatory Affairs  
DeRoyal Industries, Inc.  
200 DeBusk Lane  
Powell, Tennessee 37849

Re: K980509  
Trade Name: DeRoyal Industries, Inc.  
Infant Transport Mattress  
Regulatory Class: I  
Product Code: IMD  
Dated: February 9, 1998  
Received: February 10, 1998

Dear Ms. Matlock:

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.

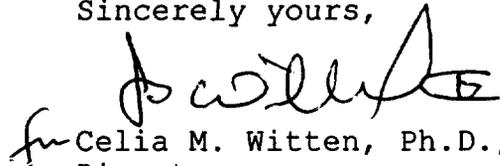
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Camille Matlock

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) 594-4659. 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,

  
for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): \_\_\_\_\_

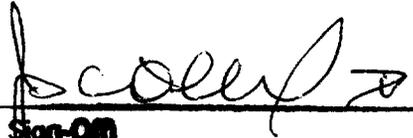
Device Name: DeRoyal Industries Inc. Infant Transport Mattress  
\_\_\_\_\_  
\_\_\_\_\_

**Indications for Use:**

The DeRoyal Industries Inc. Infant Transport Mattress is to be used to assist in maintaining infant body temperature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
Sign-Off  
of General Restorative Devices  
Number 12980509

Prescription Use X  
(Per 21 CFR § 801.109)

OR

Over-The-Counter Use \_\_\_\_\_