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DeRoyal Industries, Inc.
Pediatric Mittens

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:	August 30, 1996

DEVICE NAMES

NAME:	DeRoyal Industries, Inc. Pediatric Mittens
COMMON/USUAL NAME:	Pediatric Mittens
CLASSIFICATION NAME (if known):	Restraint, Protective (80FMQ)

PREDICATE OR LEGALLY MARKETED DEVICES

J.T. Posey Company
DeRoyal Industries, Inc.

DEVICE DESCRIPTION

The DeRoyal Industries, Inc. Pediatric Mittens are a protective restraint device that are intended for medical purposes to limit pediatric patient finger and hand movements thereby enabling examination or protection of the patient or others. Limb restraint straps that attach to the Pediatric Mittens are optional, if needed.

Device Design/Materials Used/Physical Properties: The DeRoyal Pediatric Mittens are designed similar to those marketed by other manufacturers. The Pediatric Mittens are primarily comprised of 100% polyester and cotton with hook and loop fasteners.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. Pediatric Mittens are indicated for use, at the discretion of a responsible licensed healthcare professional, to limit pediatric patient finger, hand, and/or limb movements thereby enabling examination or protection of the patient or others. The Pediatric Mittens can be attached to a bed or used alone.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Materials	Primarily comprised of 100% polyester cool knit, blue purr, and 100 % cotton white twill tape. Fasteners are made of hook and loop.	Same
Size	Infant and child	Same
Vehicles for Attachment	Attachment to bed is optional, if needed	Same
Length of use	Doctor must prescribe every 24 hours	Same
Level of Patient Activity	Finger, hand, or limb interference by pediatric patient	Same