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DeRoyal Industries, Inc.  
Pediatric Vest Restraint

510(k) Summary

K963472

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 Vest Restraint
COMMON/USUAL NAME:	Pediatric Vest Restraint
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 Vest Restraint is a protective restraint device that is intended for medical purposes to limit pediatric patient movements thereby enabling examination or protection of the patient or others. The Pediatric Vest Restraint is also available as an immobilization shirt which prevents the pediatric patient's arms from bending at the elbows with the use wooden staves (tongue depressors).

Device Design/Materials Used/Physical Properties: The DeRoyal Pediatric Vest Restraint is designed similar to those marketed by other manufacturers. The Pediatric Vest Restraint is primarily comprised of flannel or cool knit with polyester straps. The fasteners are made of a nylon hook and loop or steel nickel plated buckles.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. Pediatric Vest Restraint is indicated for use, at the discretion of a responsible licensed healthcare professional, to limit pediatric patient movements thereby enabling examination or protection of the patient or others. The Pediatric Vest Restraint is a protective restraint that can be used with a crib or bed.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Materials	Primarily comprised of cotton flannel or polyester cool knit. The straps are made of polyester twill tape and white webbing. Fasteners are made of hook and loop or steel nickel plated buckles. The stave for the immobilization shirt is made of wooden tongue depressors.	Same
Size	Infant, child (2-4)(4-6)(6-8)	Same
Vehicles for Attachment	Crib or Bed	Same
Length of use	Doctor must prescribe every 24 hours	Same
Level of Patient Activity	Vest Restraint: Limb Interference by pediatric patient Immobilization Shirt: Pediatric patient tends to bend elbows	Same