

JAN 22 1997

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**DeRoyal Industries, Inc.
Poncho Vest Restraint**

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. Poncho Vest Restraint
COMMON/USUAL NAME:	Poncho 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. Poncho Vest Restraint is a protective restraint device that is intended for medical purposes to limit movements thereby enabling examination or protection of the patient or others.

Device Design/Materials Used/Physical Properties: The DeRoyal Poncho Vest Restraint is designed similar to those marketed by other manufacturers. The Poncho Restraint is primarily comprised of cool knit or cotton 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. Poncho Vest Restraint is indicated for use, at the discretion of a responsible licensed healthcare professional, to limit movements thereby enabling examination or protection of the patient or others. The Poncho Vest Restraint is a protective restraint that is intended to be used with a bed or wheelchair.

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 or nylon. Fasteners are made of hook and loop or steel nickel plated buckles.	Same
Size	X-Small, Small, Medium, Large, X-Large, XX-Large, XXX-Large	Same
Vehicles for Attachment	Bed or Wheelchair	Same
Length of use	Doctor must prescribe every 24 hours	Same
Level of Patient Activity	Mildly agitated or disoriented	Same