

NOV 14 1996

**DeRoyal Industries, Inc.  
Sleeved/ Sleeveless Vest Restraint**

K963478

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

Device Design/Materials Used/Physical Properties: The DeRoyal Sleeved/ Sleeveless Vest Restraint is designed similar to those marketed by other manufacturers. The Sleeved/ Sleeveless Restraint is primarily comprised of cool knit, cotton, or 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. Sleeved/ Sleeveless 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 Sleeved/ Sleeveless 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 tietex, 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.	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 to moderately agitated or disoriented	Same