

NOV 14 1996

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**DeRoyal Industries, Inc.  
Reusable Limb Holder**

**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 Powell, TN 37849	CONTACT:	Camille Matlock
		DATE OF PREPARATION:	August 30, 1996

**DEVICE NAMES**

NAME: DeRoyal Industries, Inc. Reusable Limb Holder  
 COMMON/USUAL NAME: Reusable Limb Holder  
 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. Reusable Limb Holder is a protective restraint device that is intended for medical purposes to limit patient limb movements thereby enabling examination or protection of the patient or others.

Device Design/Materials Used/Physical Properties: The DeRoyal Reusable Limb Holder is designed similar to those marketed by other manufacturers. The Reusable Limb Holder is primarily comprised of a flannel and/or blue purr material. The straps are made of white webbing. The fasteners include a nylon hook and steel nickel plated buckles.

**DEVICE INTENDED USE**

The DeRoyal Industries, Inc. Reusable Limb Holder is indicated for use, at the discretion of a responsible licensed healthcare professional, to limit limb movements thereby enabling examination or protection of the patient or others. The Reusable Limb Holder can be used with a gurney, bed, or stretcher.

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

Characteristic	DeRoyal Device	Other Devices
Materials	Primarily comprised of flannel and/or blue purr material. The straps are made of white webbing. Fasteners include nylon hook and steel nickel plated buckles.	Same
Size	Universal	Same
Vehicles for Attachment	Gurney, Bed, or Stretcher	Same
Length of use	Doctor must prescribe every 24 hours	Same
Level of Patient Activity	Mildly to moderately agitated or disoriented	Same