

JAN 22 1997

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**DeRoyal Industries, Inc.
Multi-Purpose Utility Restraint/ Body 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	CONTACT:	Camille Matlock
	Powell, TN 37849	DATE OF PREPARATION:	August 30, 1996

DEVICE NAMES

NAME:	DeRoyal Industries, Inc. Multi-Purpose Utility Restraint/ Body Holder
COMMON/USUAL NAME:	Utility Restraint/ Body 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. Multi-Purpose Utility Restraint / Body Holder 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 Multi-Purpose Utility Restraint/ Body Holder is designed similar to those marketed by other manufacturers. The Multi-Purpose Utility Restraint/ Body Holder is primarily comprised of nylon or cotton.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. Multi-Purpose Utility Restraint/ Body Holder is indicated for use, at the discretion of a responsible licensed healthcare professional, to limit patient movements thereby enabling examination or protection of the patient or others. The Multi-Purpose Utility Restraint can be used with an OR table, gurney, bed, or stretcher. The Body Holder is a protective restraint which can 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 nylon or cotton. Materials also include blue purl foam, white binding, and webbing.	Same
Size	Universal	Same
Vehicles for Attachment	<u>Body Holder:</u> Bed or Wheelchair <u>Multi-Purpose Utility Restraint:</u> OR Table, Gurney, Bed, or Stretcher	Same
Length of use	Doctor must prescribe every 24 hours	Same
Level of Patient Activity	Mildly Agitated or Disoriented Surgical Patient Patient Transport	Same