DeRoyal Industries, Inc.
Super Security Restraint

510(k) Summary

$K\,9634\,7/$

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. Super Security Restraint
COMMON/USUAL NAME: Security 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. Super Security Restraint is a protective restraint device that is intended for medical purposes to limit patient movements thereby providing postural support or enabling examination or protection of the patient or others.
      Device Design/Materials Used/Physical Properties: The DeRoyal Super Security Restraint is designed similar to those marketed by other manufacturers. The Super Security Restraint is primarily comprised of cool knit material.

DEVICE INTENDED USE
The DeRoyal Industries, Inc. Super Security Restraint is indicated for use, at the discretion of a responsible licensed healthcare professional, to limit patient movements thereby providing postural support or enabling examination or protection of the patient or others. The Super Security Restraint 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	The body is comprised of Cool Knit (polyester). The binding and straps are made of polyester.	Same
Style Variations	Vest with Pelvic Holder or Vest Only	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 Tendency to Leave Bed or Wheelchair	Same