

OCT 16 1996

DeRoyal Industries, Inc.
Strait Jacket

X963463

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. Strait Jacket
COMMON/USUAL NAME: Strait Jacket
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. Strait Jacket is a protective restraint device that is intended for medical purposes to restrict patient upper body movements thereby enabling protection of the patient or others.

Device Design/Materials Used/Physical Properties: The DeRoyal Strait Jacket is designed similar to those marketed by other manufacturers. The Strait Jacket is primarily comprised of white armyduck cotton and steel nickel plated fasteners.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. Strait Jacket is indicated for use, at the discretion of a responsible licensed healthcare professional, to restrict patient upper body movements thereby enabling protection of the patient or others.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Materials	Primarily comprised of white armyduck cotton (pre-shrunk)	Same
Size	Small, Medium, Large, and Extra-Large	Same
Intended Use	Restrict upper body movement	Same
Length of use	Short term use	Same
Level of Patient Activity	Highly Agitated or Disoriented Aggressive Patient requires physical control	Same