

NOV 14 1996

K96-3469

**DeRoyal Industries, Inc.
Mittens**

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. Mittens
COMMON/USUAL NAME:	Mittens
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. Mittens are a protective restraint device that are intended for medical purposes to control hand and finger movements and/or limit limb movements thereby enabling examination or protection of the patient or others.

Device Design/Materials Used/Physical Properties: The DeRoyal Mittens are designed similar to those marketed by other manufacturers. The Mittens are primarily comprised of 100% cotton or polyester with hook and loop or buckle fasteners.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. Mittens are 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 Mittens are intended to be attached to a bed.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Materials	Primarily comprised of 100% cotton or polyester	Same
Size	Small, Medium, Large, and Extra-Large	Same
Vehicles for Attachment	Bed	Same
Length of use	Doctor must prescribe every 24 hours	Same
Level of Patient Activity	Mildly agitated Limb interference by patient	Same