

JAN 24 1997

**DeRoyal Industries, Inc.
Wheelchair Belt**

K963479

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. Wheelchair Belt
COMMON/USUAL NAME:	Wheelchair Belt
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. Wheelchair Belt is a protective restraint device that is intended for medical purposes to limit patient movements thereby helping prevent the patient from sliding in a wheelchair.

Device Design/Materials Used/Physical Properties: The DeRoyal Wheelchair Belt is designed similar to those marketed by other manufacturers. The Wheelchair Belt is primarily comprised of nylon or polyester seat belt webbing.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. Wheelchair Belt 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 DeRoyal Industries, Inc. Wheelchair Belt is intended to be used with a wheelchair only.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Materials	Primarily comprised of nylon or polyester seat belt webbing. Materials also include blue purl and foam rubber for soft padding. Fasteners are either a hook and loop or a buckle.	Same
Size	Universal	Same
Vehicles for Attachment	Wheelchair	Same
Length of use	Doctor must prescribe every 24 hours	Same
Level of Patient Activity	For patients that tend to slide in their chairs	Same