

K 963466

**DeRoyal Industries, Inc.
Pediatric Limb Holder**

FEB 13 1997

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. Pediatric Limb Holder |
| COMMON/USUAL NAME: | Pediatric Limb 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. Pediatric Limb Holder is a protective restraint device that is intended for medical purposes to limit pediatric patient limb movements thereby enabling examination or protection of the patient or others.

Device Design/Materials Used/Physical Properties: The DeRoyal Pediatric Limb Holder is designed similar to those marketed by other manufacturers. The Pediatric Limb Holder is primarily comprised of polyester straps with hook and loop fasteners.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. Pediatric Limb Holder is indicated for use, at the discretion of a responsible licensed healthcare professional, to limit pediatric patient limb movements thereby enabling examination or protection of the patient or others. The Pediatric Limb Holder can be used with an OR table, gurney, bed, or stretcher.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICE(S)

| Characteristic | DeRoyal Device | Other Devices |
|---------------------------|--|---------------|
| Materials | Primarily comprised of 100% polyester twill tape and white webbing. Materials also include blue purr foam or white kodel. Fasteners are made of hook and loop. | Same |
| Size | Infant, child, teen | Same |
| Vehicles for Attachment | OR Table, gurney, bed, or stretcher | Same |
| Length of use | Doctor must prescribe every 24 hours | Same |
| Level of Patient Activity | Limb Interference by Pediatric Patient | Same |