

JAN 22 1997

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

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

Device Design/Materials Used/Physical Properties: The DeRoyal Restrictive Limb Holder is designed similar to those marketed by other manufacturers. The Restrictive Limb Holder is primarily comprised of leather, neoprene, and soft kodel with nylon or polyester webbing straps. The types of fasteners include hook and loop, delrin, and various types that are steel nickel plated.

DEVICE INTENDED USE

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

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICE(S)

| Characteristic | DeRoyal Device | Other Devices |
|---------------------------|---|---------------|
| Materials | Primarily comprised of leather, neoprene, and soft kodel material with webbing straps. The types of fasteners include hook and loop, delrin, and various types that are steel nickel plated | Same |
| Size | Universal | Same |
| Vehicles for Attachment | Gurney, Bed, or Stretcher | Same |
| Length of use | Doctor must prescribe every 24 hours | Same |
| Level of Patient Activity | Highly agitated or violent | Same |