K963439

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SAFETY AND EFFECTIVENESS SUMMARY

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Trade Name: Protective Restraints
Common Name: Pediatric limb holders
Classification Name: Protective Restraints

The devices included in this 510(k) submission limit limb movement and/or finger movement. The product is closed around the patient by encircling the wrists, hands, or ankles. The product is secured to the hospital bed or crib via straps. These straps are securely connected to the hospital bed or crib by quick release knots or with the use of a safety pin.

These products are intended to limit limb movement or finger movement in a hospital bed or crib.

The devices used for comparative purposes are identical to the pediatric limb holders as described in this submission and produced or sold by the J.T. Posey Co. This premarket submission is submitted in response to the agency's final rule published on March 4, 1996 in the Federal Register 21 CFR 880 and 21 CFR 890 Medical Devices, Protective Restraints - Revocation of Exemptions from 510(k) Premarket Notification Procedures and Current Good Manufacturing Practice Regulation. The June 13, 1996 Meeting Minutes, HIMA Body Holder Task Force and FDA CDRH established the rationale for which devices would be used for comparison:

> *"Predicate device*
>
> FDA indicated that it would be appropriate for manufacturers to reference their current products as legally marketed devices for comparison purposes in their submissions. It would also be appropriate to reference any approved 510(k)s that manufacturers have submitted for their products."

The pediatric limb holders are currently exempt from 510(k) Premarket Notification Procedures and Good Manufacturing Practice Regulations and are **legally marketed** by JT Posey Co. as of the date of this submission, August 30,1996. The limb holders have been manufactured and in commercial distribution for up to 20 years.