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Posey Company

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K963442

SAFETY AND EFFECTIVENESS SUMMARY

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August 30, 1996
Revised: November 18, 1996

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Reference Number: K963442

Trade Name: Protective Restraints
Common Name: Jackets and Vests
Classification Name: Protective Restraints

The devices included in this 510(k) submission support the torso area. The product is closed around the patient by one or more of the following: criss crossing the fabric and straps, a zipper, hook and loop, or tie strings. The product is secured to the bed, geriatric chair, wheelchair, or gurney via straps. These straps are securely connected to the bed, geriatric chair, or wheelchair by one or more of the following: knots, double D rings, hook and loop, standard buckles, or quick release buckles.

These products are intended to hinder egress of a patient and/or assist body alignment in a hospital bed, geriatric chair, wheelchair, or gurney.

The devices used for comparative purposes are identical to the jackets and vests 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) Pre-market 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 jackets and vests 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.