

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1 of 2

**NAME OF FIRM:** DePuy, Inc.  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988  
Registration No.: 1818910

**FIRM CONTACT:** Arlene Saull, RAC  
Manager, Medical Device Submissions

**TRADE NAME:** DePuy Mesh Vest Restraint with Sleeves  
DePuy Wrist/Ankle Restraint

**COMMON NAME:** Protective Restraints

**CLASSIFICATION:** Class I per 21 CFR, 880.6760 Protective Restraint

**DEVICE PRODUCT CODE:** 80 FMQ Restraint, Protective

**SUBSTANTIALLY EQUIVALENT DEVICES:**  
J. T. Posey Co. Vest Restraint  
J. T. Posey Co. Limb Holders

**DEVICE DESCRIPTION AND INTENDED USE:****Vest Restraint:**

The body of the vest restraint is constructed from two main pattern pieces, a front and a back which are cut from light weight polyester mesh fabric. The back is split down the center which results in there being two identical back pieces. The back opening facilitates the application of the garment to the patient. It contains a hook and loop closure which extends from the neck through to the bottom of the vest. The vest comes equipped with long straps attached just below waist level for securing the patient to the chair, wheelchair or bed; ties at the waist to adjust for proper fit; underarm loops to which the optional 54" long straps can be attached if additional support is required; and a modified v-neck. It is supplied in five sizes from X-small to X-large to fit chests from 28" to 56". It may be hand washed in warm water and air dried.

**Wrist/Ankle Restraints:**

The wrist/ankle restraints are simply constructed from a polyester pile fabric with a knitted backing. They are secured to the wrist or ankle with a hook and loop closure and are supplied with a long strap which is used to secure the wrist/ankle restraint to a chair, wheelchair or bed. The wrist/ankle restraints are available with two types of buckles on the long straps; sliding metal buckle or a white (nylon acetal) quick-release buckle. Both styles are provided in one universal adult size. They may be hand washed in warm water and air dried.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The DePuy Mesh Vest Restraint with Sleeves and the DePuy Wrist/Ankle Restraints are substantially equivalent to protective restraints marketed by the J. T. Posey Co. based on their similarities in design, construction, materials, fasteners, and intended uses.