

## Summary of Safety & Effectiveness Data for the Johnson & Johnson Safety Vests

Johnson & Johnson Professional, Inc.  
325 Paramount Drive  
Raynham, Massachusetts 02767

1. **Contact Person**

Johanna Adler, Assoc. Regulatory Affairs Specialist, (508) 828-3268.

2. **Device Name**

**Proprietary Name:** Johnson & Johnson Safety Vests  
**Common Name:** Safety Vests  
**Classification Name:** Protective Restraint  
**Regulatory Class:** Class I by 21 CFR § 880.6760  
**Product Code:** 80 FMQ  
**Owner/ Operator #** 9001269

3. **Device Classification**

Classification for Johnson & Johnson Safety Vests has been placed in Class I by 21 CFR § 880.6760

4. **Statement of Substantial Equivalence**

The safety and effectiveness of the Johnson & Johnson Safety Vest and the Safety Vest Poncho Style is substantiated by its similarity in design, characteristics, and indications for use, to the currently marketed Posey Waist & Chest Vest and the Posey Criss-Cross Vest, by J.T. Posey Company.

5. **Indications for Use**

The Johnson & Johnson Safety Vests are designed to protect patients that are at risk of self injury or interruption of medical care by restraining them . These products can be used in restraining patients to a bed or chair.

6. **Physical Description**

The Johnson & Johnson Safety Vests are constructed of lightweight nylon mesh with webbed tie straps and shoulder loops. These vests may be attached to either a chair or a bed.

## Summary of Safety & Effectiveness Data for the Johnson & Johnson Limb Holders

Johnson & Johnson Professional, Inc.  
325 Paramount Drive  
Raynham, Massachusetts 02767

### 1. Contact Person

Johanna Adler, Assoc. Regulatory Affairs Specialist, (508) 828-3268.

### 2. Device Name

**Proprietary Name:** Johnson & Johnson Limb Holders  
**Common Name:** Limb Holders  
**Classification Name:** Protective Restraint  
**Regulatory Class:** Class I by 21 CFR § 880.6760  
**Product Code:** 80 FMQ  
**Owner/ Operator #** 9001269

### 3. Device Classification

Classification for Johnson & Johnson Limb Holders has been placed in Class I by 21 CFR § 880.6760

### 4. Statement of Substantial Equivalence

The safety and effectiveness of the Johnson & Johnson Canvas Limb Holder and the Economy Limb Holder is substantiated by its similarity in design, technological characteristics, and indications for use, to the currently marketed Posey-Van Pelt Limb Holder and the Posey Economy Limb Holder, by J.T. Posey Company.

### 5. Indications for Use

The Johnson & Johnson Limb Holders are designed to protect patients that are at risk of self injury or interruption of medical care by restraining them . These products can be used in restraining patients to a bed or chair.

### 6. Physical Description

The Johnson & Johnson Canvas Limb Holder is constructed of a cotton canvas wrist protector with a soft cotton lining, and a polyester strap. The Economy Limb Holder is constructed of a nylon laminated foam with hook and loop closure and polyester straps.