

K963430

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**510(k) SUMMARY****1. PERSONNEL AND DATE (807.92(a)(1))****1.1. Submitter**

Kenad SG Medical Inc.  
2692 Huntley  
Memphis, TN 38132

**1.2.. Contact Person**

Kenneth Elmore  
President and CEO  
Kenad SG Medical Inc.

**1.3.. Date Of summary Preparation**

This summary was prepared in July 1996.

**2. DEVICE NAME (807.92(a)(2))**

As noted in the Cover Letter, three similar devices are grouped within this 510(k) notification. These devices differ only in minor design aspects. Their function, application and use is identical.

**2.1. Trade Or Proprietary Name**

Vest Restraint is the trade or proprietary name for the devices subject to this Premarket Notification Submission. Within this name are the following:

Pediatric Patient Protective Vest (Without Sleeves)  
Patient Protective Vest (Without Sleeves)  
Patient Protective Vest (With Sleeves)  
Patient Protective Vest (With Sleeves With Tails)

These devices are available in sizes: X-Small, Small, Medium, Large, X-Large and XX-Large.

**2.2. Common Or Usual Name**

Protective Restraint 21CFR 880.6760

### 3. LEGALLY MARKETED DEVICE (807.92(a)(3))

The Kenad Vest Restraints subject to this Premarket Notification Submission are comparable to Vest Restraints from Danek Medical, Inc. Danek successfully filed a Premarket notification for their Vest Restraints at Document Control number K823815, January 17, 1983.

### 4. DEVICE DESCRIPTION (807.92(a)(4))

#### 4.1. General Description

The Kenad Vest Restraints subject to this Premarket Notification are devices that comprise the following modules, cited in this document

Vest-	blue, flame retardant polyester cotton twill fabric.
Shoulder Ring-	nickle plated, polished metal buckle.
Side Strap-	flexible, polypropylene material.
Quick Release Buckle-	plastic buckle.
Anchor Strap-	flexible, polypropylene material.

#### 4.2. How Vest Restraints Function

Vest Restraints are placed about the upper body as a jacket. The jacket is fixed comfortably, yet snugly in place by crossing the side straps. The restraint is then affixed to a stationary part of a bed or chair via the Side Strap, Quick Release Buckle and Anchor Strap.

### 5. INTENDED USE (807.92(a)(5))

#### 5.1. Indications

Kenad Vest Restraints are indicated for medical purposes where patient movement must be limited to the extent necessary for treatment, examination, protection of the patient or others, or posture control.

**5.2. Patient Population**

Kenad Vest Restraints are used with adults and children.

**5.3. Indications Different From Substantially Equivalent Device**

Indications and patient populations for the Kenad devices are identical to the legally marketed device cited in this document

**6. COMPARISON TO LEGALLY MARKETED DEVICE (807.92(a)(6))**

Kenad Vest Restraints are comparable to vest restraints from Danek Medical, Inc. A comparison of these devices are provided in this Premarket Notification Submission.

**7. PERFORMANCE DATA (807.92(b))**

More than 5000 Kenad Vest Restraints were sold over the last 5 years. Assuming 100% usage, there have been more than 5000 patient contacts with Vest Restraints over the last 5 years. During this time, Kenad received no patient injury or product failure complaints about Vest Restraints.

**8. SAFETY, EFFICACY AND PERFORMANCE CONCLUSION (807.92(b)(3))**

The absence of patient injury or product failure complaints following approximately 5000 product uses over 5 years indicates Kenad Vest Restraints are safe and effective.