

K963421

NOV 22 1996

**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 thru August 1996.

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

As noted in the Cover Letter, four 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**

Waist Holder is the trade or proprietary name for the devices which are the subject of this Premarket Notification Submission. Within this name are four Kenad Waist Holders.

KENAD Catalog #	Size
50-3400	Pediatric
50-3500	Adult
50-3600	Adult Universal w/Slit
50-3700	Adult X-Wide

**2.2. Common Or Usual Name**

Protective Restraint 21CFR 880.6760

knad8

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

The Kenad Waist Holder subject to this Premarket Notification Submission is comparable to Waist Holder from Danek Medical, Inc. Danek successfully filed a Premarket notification for waist holders at Document Control number K823815, January 17, 1983.

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

#### **4.1. General Description**

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

Belt-	Blue, polyurethane foam
Side Strap-	Flexible, polypropylene
Quick Release Buckle-	Plastic buckle
Anchor Strap-	Flexible, polypropylene

#### **4.2. How Waist Holder Functions**

Waist Holders are placed comfortably around the waist as a belt. The Side Straps are then affixed by Quick Disconnect to an Anchor Strap affixed to an immovable object either on a bed, for bed application, or on a chair, for chair application.

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

#### **5.1. Indications**

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

#### **5.2. Patient Population**

Kenad Waist Holders 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 Waist Holders are comparable to Waist Holders from Danek Medical, Inc. A comparison of these devices are provided in this Premarket Notification Submission.

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

More than 10,000 Kenad Waist Holders were sold over the last 5 years. Assuming 100% usage, there have been more than 10,000 patient contacts with Waist Holders over the last 5 years. During this time, Kenad received no patient injury or product failure complaints about the Waist Holders.

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

The absence of patient injury or product failure complaints following more than 10,000 product uses over 5 years indicates the Kenad Waist Holders are safe and effective.