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K963374

Morrison Medical Products  
Torso/Waist Restraint

**510(k) Summary**

**1. 1. Submitter's name, Address and Contact Person**

Submitter

Morrison Medical Products Inc.  
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Contact Person

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Date Summary Prepared - November 7, 1996

**2. Name of Device:**

Morrison Medical Torso/Waist Restraint

**3. Name of Predicate Device(s)**

Morrison Medical Torso/Waist Restraint

**4. Description of Device**

The Morrison Medical Torso/Waist Restraint is intended to be used by emergency personnel to help secure a patient at the torso and waist, while lying on a cot or stretcher, in an ambulance or other emergency vehicle while in transport to a hospital or other critical care facility. The restraint can be used in the supine or elevated positions.

The Morrison Medical Torso/Waist Restraint is constructed by combining two adjustable, nylon, "over-the-shoulder" straps that secure the upper torso and two adjustable nylon straps that secure the waist. All four straps are joined at the waist and are secured with a metal push button buckle and metal connectors.

The nylon webbing is available in multiple colors.

**5. Statement of Intended Use**

The Morrison Medical Torso/Waist Restraint is intended to help secure a patient at the torso and waist in an ambulance or other emergency vehicle while in transport to a hospital or other critical care facility.



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**6. Statement of Technological Characteristics of the Device**

The Morrison Medical Torso/Waist Restraint is constructed by combining two adjustable, nylon, "over-the-shoulder" straps that secure the upper torso and two adjustable nylon straps that secure the waist. All four straps are joined at the waist and are secured with a metal push button buckle and metal connectors. The Nylon webbing is available in multiple colors.

The subject devices are identical in intended use, design, materials, manufacturing process, physical and mechanical specifications and issues of safety and effectiveness to the devices prior to the submission of this notification. The only difference is that the product labeling has been revised to comply with the Agency's labeling requirements set forth in the draft "Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints" dated December 1995.

**7. Biocompatibility Assessment**

The subject devices are identical in components materials to the predicate devices. Morrison Medical Products is not aware of any reports or complaints of skin irritation associated with the materials used in these devices. A biocompatibility review of these materials indicated little potential to evoke an adverse reaction.

**8. Conclusion**

Based upon the information presented above it is concluded that the proposed Morrison Medical Torso/Waist Restraint is safe and effective for its intended use and is substantially equivalent to the predicate device.