

Morrison Medical Products
Disposable Restraint Strap**Safety and Effectiveness Summary****1. Submitter's name, Address and Contact Person**SubmitterMorrison Medical Products
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2. Name of Device:

Morrison Medical Disposable Restraint Strap

3. Name of Predicate Device(s)

Morrison Medical Disposable Restraint Strap

4. Description of Device

The Morrison Medical Disposable Restraint Strap is intended to help secure a patient's body while lying on a backboard. The straps are constructed of an acrylic coated polyester woven material with an adhesive band on each end of the strap. The patient is secured to the backboard by lying the strap across the patient's body and peeling the release paper from the strap. The strap is woven through the hand hold in the backboard and stuck back onto the polyester strap. After use the strap is cut off with scissors.

5. Statement of Intended Use

The Morrison Medical Disposable Restraint Strap is intended to help secure a patient's body while lying on a backboard.

6. Statement of Technological Characteristics of the Device

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.

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7. Biocompatibility

The materials used to manufacture this device are identical to a similar marketed device under comparable conditions of use. Morrison Medical Products is not aware of any reports or complaints of skin irritation associated with the materials used in this device.

8. Conclusion

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