

Morrison Medical Products
Wrist Restraint

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter

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Contact Person

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2. Name of Device:

Morrison Medical Wrist Restraint

3. Name of Predicate Device(s)

Morrison Medical Wrist Restraint

4. Description of Device

The Morrison Medical Wrist Restraint is constructed of a nylon woven webbing and metal D-Ring. There is nylon hook and loop material sewn onto the nylon webbing. This nylon hook and loop combination is intended to secure the wrist restraint to the patient. The Wrist Restraint is intended to restrain the patient to a chair, cot or stretcher.

5. Statement of Intended Use

The Morrison Medical Wrist Restraint is intended to be a protective limb restraint that limits the patient's movement to the extent necessary for treatment, examination, or protection of the patient or others. The device can be used in the supine or sitting positions.

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 subject devices are identical in component 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 Wrist Restraint is safe and effective for its intended use and is substantially equivalent to the predicate device.