MORRISON MEDICAL PRODUCTS

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Morrison Medical Products
Ankle Restraint System

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter	Contact Person
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Date Summary Prepared - August 26, 1996

2. Name of Device:

Ankle Restraint System

3. Name of Predicate Device(s)

Ankle Restraint System

4. Description of Device

In recent years there has been considerable effort in the health care community to assure that restraints are used only when needed, usually with patient consent and that the least restrictive restraint be used. Morrison Medical Products has developed the Ankle Restraint System to help serve in this purpose. The Ankle Restraint System is designed for situations requiring patient control. The Ankle Restraint System is a restraint system that secures the patient's ankles in a fixed position. It consists of two individual ankle restraints that are permanently attached at a specific distance apart from each other to a long security strap. The security strap is constructed using a nylon woven webbing that is 2 inches wide and 17 inches long. Straps attached to both ends of the security strap secure the ankle restraint system to a cot or stretcher. The individual ankle restraints are also constructed using a nylon woven webbing. A nylon hook and loop closure is secured to the webbing and is used to securely close the ankle restraint.

5. Statement of Intended Use

The Ankle Restraint System is intended to be used in situations requiring patient control while the patient is lying on a cot or stretcher. The Ankle Restraint System is intended to secure the patient's ankles by keeping them in a fixed position.

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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.

7. Biocompatibility Assessment

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 Ankle Restraint System is safe and effective for its intended use and is substantially equivalent to the predicate device.

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