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Heelbo, Inc.

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NOV - 7 1996

Heelbo, Inc.
Heelbo ER Wrist Restraint

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter
Heelbo, Inc.
1134 N. Homan Ave.
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Contact Person
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Date Summary Prepared - August 23, 1996

2. Name of Device:

Heelbo ER Wrist Restraint

3. Name of Predicate Device

Heelbo ER Wrist Restraint

4. Description of Device

The Heelbo ER 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 ER Wrist restraint can be used in the supine and elevated positions.

The Heelbo ER Wrist Restraint combines a neoprene and nylon cuff limb holder with a Velcro® fastener, Quick-Release closure, Double D-Rings, and two straps. The patient's wrist is secured into the neoprene and nylon cuff by Velcro® hook and loop straps and a Quick release closure. The attached webbed straps are then wrapped around the bed or gurney frame and are woven through a Double D-ring closure. This d-ring closure allows the caregiver to quickly and easily disconnect the restraint from the bed or gurney frame by eliminating time consuming untying of knots. The Heelbo ER Wrist Restraint are machine washable.

5. Statement of Intended Use

The Heelbo ER 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 elevated positions.

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6. Statement of Technological Characteristics of the Device

The Heelbo ER Wrist Restraint combines a neoprene and nylon cuff limb holder with a Velcro® fastener, Quick-Release closure, Double D-Rings, and two straps. The patient's wrist is secured into the neoprene and nylon cuff by Velcro® hook and loop straps and a Quick release closure. The attached webbed straps are then wrapped around the bed or gurney frame and are woven through a Double D-ring closure. This d-ring closure allows the caregiver to quickly and easily disconnect the restraint from the bed or gurney frame by eliminating time consuming untying of knots.

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. Heelbo, Inc., 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 Heelbo ER Wrist Restraint is safe and effective for its intended use and is substantially equivalent to the predicate device.