

OCT 18 1996

Heelbo, Inc.

Heelbo Quilted Limb Holder with Double D-Ring, Quick-Release Snap and Strap

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter

Heelbo, Inc.
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Contact Person

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Date Summary Prepared - July 17, 1996

2. Name of Device:

Heelbo Quilted Limb Holder with Double D-Ring, Quick-Release Snap and Strap

3. Name of Predicate Device

Heelbo Quilted Limb Holder with Double D-Ring, Quick-Release Snap and Strap

4. Description of Device

Heelbo Quilted Limb Holder with Double D-Ring, Quick-Release Snap and Strap is a disposable quilted limb holder with a Velcro® fastener, Double D-Ring, Quick-Release Snap and Straps that secure to a bed, gurney, chair or wheelchair. The Heelbo Quilted Limb Holder with Double D-Ring, Quick-Release Snap and Strap 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 Heelbo Quilted Limb Holder allows for wrist adjustment to provide a secure fit without cinching. The Double D-Ring is simple to use and allows the caregiver easy access to the patient. Also, the adjustable Double D-Ring and Quick-Release Snap allow for supine and sitting positions. The Heelbo Quilted Limb Holders are machine washable.

The Heelbo Quilted Limb Holder with Double D-Ring, Quick-Release Snap and Strap is available in the following sizes:

Stock No. 9350

Small-Regular / cuff size: 11 1/2" long
strap: 3/4" wide, 60" long

Stock No. 9360

Large-X-Large / cuff size: 13 1/2" long
strap: 3/4" wide, 60" long

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5. Statement of Intended Use

Heelbo Quilted Limb Holder with Double D-Ring, Quick-Release Snap, and Strap 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

Heelbo Quilted Limb Holder with Double D-Ring, Quick-Release Snap and Strap is a disposable quilted limb holder with a Velcro® fastener, Double D-Ring, Quick-Release Snap and Straps that secure to a bed, gurney, chair or wheelchair. The Heelbo Quilted Limb Holder with Double D-Ring, Quick-Release Snap and Strap 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 Heelbo Quilted Limb Holder allows for wrist adjustment to provide a secure fit without cinching. The Double D-Ring is simple to use and allows the caregiver easy access to the patient. Also, the adjustable Double D-Ring and Quick-Release Snap allow for supine and sitting positions.

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 [501(k)] Submissions for Protective Restraints" dated December 1995

7. Biocompatibility Assessment

The subject devices are identical in component materials to the predicate devices. The suppliers of the materials use in the fabrication of these devices have stated that there is a history of safe use of their materials in the clothing and garment industry. In addition, Heelbo, Inc., is not aware of any reports or complaints of skin irritation associated with these materials.

Conclusion

Based upon the information presented above it is concluded that the proposed Heelbo Quilted Limb Holder with Double D-Ring, Quick-Release Snap, and Strap is safe and effective for its intended use and is substantially equivalent to the predicate device.