

OCT 11 1996

Heelbo, Inc.
Wrap Around Vest

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 - August 19, 1996

2. Name of Device:

Heelbo Wrap Around Vest

3. Name of Predicate Device(s)

Heelbo Wrap Around Vest

4. Description of Device

The Heelbo Wrap Around Vest is a crisscross-style safety vest. The Heelbo Wrap Around Vest is intended to help support and help prevent a patient from slumping or sliding forward while seated in a wheelchair or geriatric chair. The Heelbo Wrap Around Vest is also intended to limit the patient's movement while lying on a bed or gurney to prevent the patient from falling out of bed or climbing over the side rails.

The vest is secured to the bed or wheelchair frame with two straps. There are also loops sewn to the shoulder area of the vest in the event extra support is needed.

The Wrap Around Vest is available with a knotless system (quick disconnect option). This option allows the caregiver to quickly and easily disconnect the restraint from the chair or bed frame by eliminating time consuming untying of knots (a picture of the loop accessory is attached to this section).

The Wrap Around Vest is available in a poly/cotton blend or a polyester mesh material. Five sizes accommodate a wide range of patients. The Wrap Around Vest is made of durable machine washable materials and is color coded for easy size identification.

Heelbo, Inc.
Wrap Around Vest

The following chart shows product availability:

The Wrap Around Vest Is Available in the following Sizes and Configurations

Series	Material	Size of Vest	Color
9420 9420K*	Poly/Cotton blend	x-small	White
		small	Yellow
		medium	Blue
		large	Green
		x-large	Beige
9420B*	Polyester Mesh material	x-small	White bias on white breezewear
		small	Yellow bias on white breezewear
		medium	Blue bias on white breezewear
		large	Green bias on white breezewear
		x-large	Beige bias on white breezewear

* K=Knotless, B=Breezewear

5. Statement of Intended Use

The Heelbo Wrap Around Vest is intended to help support and help prevent a patient from slumping or sliding forward while seated in a wheelchair or geriatric chair. The Heelbo Wrap Around Vest is also intended to limit the patient's movement while lying in bed or on a gurney to prevent the patient from falling out of bed or climbing over the side rails.

6. Statement of Technological Characteristics of the Device

The Heelbo Wrap Around Vest is a crisscross-style safety vest. The Heelbo Wrap Around Vest is intended to help support and help prevent a patient from slumping or sliding forward while seated in a wheelchair or geriatric chair. The Heelbo Wrap Around Vest is also intended to limit the patient's movement while lying on a bed or gurney to prevent the patient from falling out of bed or climbing over the side rails.

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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

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.

8. Conclusion

Based upon the information presented above it is concluded that the proposed Heelbo Wrap Around Vest is safe and effective for its intended use and is substantially equivalent to the predicate device.