

OCT - 9 1996

Heelbo, Inc.  
Quilted Torso Restraint

## 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 8, 1996

### 2. Name of Device:

Heelbo Quilted Torso Restraint

### 3. Name of Predicate Device(s)

Heelbo Quilted Torso Restraint

### 4. Description of Device

The Heelbo Quilted Torso Restraint is a reinforced, padded belt 4½ inches wide by 33⅓ inches long. The Quilted Torso Restraint is designed with polyester webbed strapping that is wrapped around the frame of a bed or gurney and threaded through a drop-jaw buckle to secure the patient at the torso or legs.

### 5. Statement of Intended Use

The Heelbo Quilted Torso Restraint is intended to help secure a patient at the torso or legs while lying on a bed or gurney.

### 6. Statement of Technological Characteristics of the Device

The Heelbo Quilted Torso Restraint is a reinforced, padded belt 4½ inches wide by 33⅓ inches long. The Quilted Torso Restraint is designed with polyester webbed strapping that is wrapped around the frame of a bed or gurney and threaded through a drop-jaw buckle to secure the patient at the torso or legs.

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

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