

# Heelbo, Inc.

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K963060

**NOV 4 1996**

Heelbo, Inc.  
Security Belt

## 510(k) Summary

### 1. Submitter's name, Address and Contact Person

Submitter

Heelbo, Inc.  
1134 N. Homan  
Chicago, IL 60651

Contact Person

Joseph S. Tokarz, Manager, Regulatory Affairs  
Hollister Incorporated  
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Date Summary Prepared - November 1, 1996

### 2. Name of Device:

Heelbo Security Belt

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

Heelbo Security Belt

### 4. Description of Device

The Heelbo Security Belt is a padded belt 4¾ inches wide by 22 inches long with cotton webbed straps sewn onto both ends. The webbed straps tie to the frame of the wheelchair or geriatric chair to help secure the patient while seated.

### 5. Statement of Intended Use

The Heelbo Security Belt is intended to help secure the patient while seated in a wheelchair or geriatric chair.

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

The Heelbo Security Belt is a padded belt 4¾ inches wide by 22 inches long with cotton webbed straps sewn onto both ends. The webbed straps tie to the frame of the wheelchair or geriatric chair to help secure the patient while seated.

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is that the product labeling has been revised to comply with the Agency's labeling requirements set forth in the draft Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints dated December 1995.

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## **7. Biocompatibility Assessment**

The subject devices are identical in components materials to the predicate devices. The suppliers of the materials used 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 Security Belt is safe and effective for its intended use and is substantially equivalent to the predicate device.