

OCT 18 1996

Heelbo, Inc.  
The Inch Quilted Limb Holder

## **Safety and Effectiveness Summary**

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

Submitter

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

Contact Person

Joseph S. Tokarz, Manager, Regulatory Affairs  
Hollister Incorporated  
2000 Hollister Drive  
Libertyville, IL 60048  
Ph: (847)680-2849, Fax: (847)918-3860

Date Summary Prepared - July 17, 1996

### **2. Name of Device:**

The Inch Quilted Limb Holder with quick release snap closure

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

The Inch Quilted Limb Holder with quick release snap closure

### **4. Description of Device**

The Inch Quilted Limb Holder with quick release snap closure is a quilted limb holder with a Velcro® fastener, quick release snap closure and straps that secure to a bed, gurney, chair, geri-chair or wheelchair. The Inch Quilted Limb Holder with quick release closure 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 Inch allows for wrist adjustment to provide a secure fit without cinching. The knotless quick release snap closure is simple to use and allows the caregiver fast and easy access to the patient. A slide harness allows for supine or sitting positions. The Inch limb holders are machine washable.

The Inch Quilted Limb Holders are available in the following sizes, variations and types of assembly to accommodate the various needs of the user. (See chart on next page)

Heelbo, Inc.  
The Inch Quilted Limb Holder

### The Inch Quilted Limb Holder Availability

Unit Pack	Series	Cuff Size(inches)	Description
6 pr	7700	Small/Reg up to 11½" long	unassembled quick release snap closure strap and one tie down strap
6 pr	7710	Large/XL up to 12½" long	
6 pr	7715	Small/Reg up to 11½" long	pre-threaded quick release snap closure strap and one tie down strap
6 pr	7718	Large/XL up to 12½" long	
6 pr	7700-DS	Small/Reg up to 11½" long	unassembled quick release snap closure strap and two tie down straps
6 pr	7710-DS	Large/XL up to 12½" long	
6 pr	7720	Small/Reg up to 11½" long	pre-threaded quick release snap closure strap and one quick release loop accessory (quick release loop accessory is replacement part*, series 7775)
6 pr	7725	Large/XL up to 12½" long	
6 pr	7735	Youth up to 9" long	
6 pr	7730	toddler up to 9" long	toddler quilted limb holder with Velcro® and two tie down straps
10 ea	7775	replacement part	quick release loop accessory**

\* a quick release loop accessory that is secured to a chair/bed allows for fast release and eliminates the step of untying knots or cutting straps.

\*\* Series 7775 is included with Series 7720, 7725 and 7735. It is also sold separately as a replacement part for Series 7720, 7725 and 7735.

#### 5. Statement of Intended Use

The Inch Quilted Limb Holder with quick release closure 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

The Inch Quilted Limb Holder with quick release snap closure is a quilted limb holder with a Velcro® fastener, quick release snap closure and straps that secure to a bed, gurney, chair, geri-chair or wheelchair. The Inch Quilted Limb Holder with quick release closure 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 Inch allows for wrist adjustment to provide a secure fit without cinching. The knotless quick release snap closure is simple to use and allows the caregiver fast and easy access to the patient. A slide harness allows for supine or sitting positions.

Heelbo, Inc.  
The Inch Quilted Limb Holder

## **6. Statement of Technological Characteristics of the Device (con't)**

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.

## **8. Conclusion**

Based upon the information presented above it is concluded that the proposed Inch Quilted Limb Holders are safe and effective for their intended use and are substantially equivalent to the predicate device.