Heelbo, Inc.

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K962778

OCT - 9 1996

Heelbo, Inc.
The L-Bow Arm Restraint

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter
Heelbo, Inc.
1134 N. Homan Ave.
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Contact Person
Joseph S. Tokarz; Manager, Regulatory Affairs
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Date Summary Prepared - July 15, 1996

2. Name of Device:

L-Bow Arm Restraint

3. Name of Predicate Device(s)

- L-Bow Arm Restraint

4. Description of Device

The L-Bow Arm Restraint is constructed of a flexible plastic insert that is covered with soft polyester foam fabric held securely closed with Velcro® fasteners. The L-bow Arm Restraint is wrapped around the patient's elbow and is intended to limit the patient's movement, particularly away from their face and IV tubing, by keeping their arm in an extended position. The Velcro® fasteners are easy to use and offer a secure firm hold. The L-Bow may be machine washed.

The L-Bow is available in three sizes to accommodate various infant, toddler and youth sizes and two sizes to accommodate adults. The following are the sizes available:

Pediatric			Adult		
Size	**Dimensions (inches)**	**Stock No.**	**Size**	**Dimensions (inches)**	**Stock No.**
Infant	7" x 5"	9380	Medium	10" x 11"	9395
Toddler	8" x 6"	9385	Large	12" x 13"	9398
Youth	10" x 8.5"	9390			

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5. Statement of Intended Use

The L-Bow Arm Restraint fits over the patient's elbow and is intended to limit the patient's movement, particularly away from their face and IV tubing, by keeping their arm in an extended position.

6. Statement of Technological Characteristics of the Device

The L-Bow Arm Restraint is constructed of a flexible plastic insert that is covered with soft polyester foam fabric held securely closed with Velcro® fasteners. The L-bow Arm Restraint is wrapped around the patient's elbow and is intended to limit the patient's movement, particularly away from their face and IV tubing, by keeping their arm in an extended position. The Velcro® fasteners are easy to use and offer a secure firm hold.

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 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 L-Bow Arm Restraint is safe and effective for its intended use and is substantially equivalent to the predicate device.