K980640

Heelbo, Inc.

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Chicago, IL 60651
312/489-7711

Telex RCA 297-248
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MAY 1 1998

Heelbo, Inc.
Waist and Chest Vest

510(k) Summary

1. Submitter's name, Address and Contact Person

Submitter
Heelbo, Inc.
1134 N. Homan Ave.
Chicago, IL 60048

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 - February 17, 1998

2. Name of Device:

Heelbo Waist and Chest Vest

3. Name of Predicate Device(s)

Heelbo Pullover Poncho, K963099
Heelbo Life Jacket Poncho with Crotch Support, K963041
Posey®Waist and Chest Vest

4. Description of Device

The Heelbo Waist and Chest Vest is a poncho style safety vest that has two sets of two straps that are secured to a wheelchair to support the upper torso. When all the straps are connected per the instructions the Heelbo Waist and Chest Vest is intended to help prevent the patient from slumping or sliding forward while seated in a wheelchair and helps to prevent a patient from falling out of bed. The Waist and Chest Vest is available in a polyester/cotton blend (9340) or a polyester mesh material (9340B).

5. Statement of Intended Use

The Heelbo Waist and Chest Vest is intended to 1) help support and help prevent a patient from slumping or sliding forward while seated in a wheelchair or geriatric chair and 2) help prevent a patient from falling out of bed or climbing over slide rails.

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6. Statement of Technological Characteristics of the Device

The proposed device is substantially equivalent to the predicate devices. The following is a chart comparing the devices.

Characteristics	**Heelbo Waist and Chest Vest (proposed device)**	**Posey®Waist and Chest Vest (predicate device)**
Intended Use	1) help support and help prevent a patient from slumping or sliding forward while seated in a wheelchair or geriatric chair 2) help prevent a patient from falling out of bed or climbing over slide rails.	Same
Materials	Polyester Cotton Blend Polyester Mesh	Cotton Breezeline Mesh
Number of straps	2	2
Where used	wheelchair, geriatric chair, bed	wheelchair, geriatric chair, bed

7. Biocompatibility

Materials used in the construction of the proposed device are identical to materials reviewed and cleared under K963099 "Heelbo Pullover Poncho" and K963041 "Heelbo Life Jacket Poncho w/crotch Support." 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, over a fifteen year period using these materials, Heelbo Inc., is not aware of any adverse biological incidence.

8. Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1998

Heelbo, Incorporated
C/O Mr. Joseph S. Tokarz
Manager, Regulatory Affairs
Hollister Incorporated
2000 Hollister Drive
Libertyville, Illionis 60048

Re: K980640
Trade Name: Heelbo Waist and Chest Vest
Regulatory Class: I
Product Code: FMQ
Dated: February 17, 1998
Received: February 19, 1998

Dear Mr. Tokarz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

b.

Statement of Intended Use

510(k) Number (if Known): K980640
Device Name: Waist and Chest Vest

Intended Use:

The Heelbo Waist and Chest Vest is intended to 1) help support and help prevent a patient from slumping or sliding forward while seated in a wheelchair or geriatric chair and 2) help prevent a patient from falling out of bed or climbing over slide rails.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter-Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980640