NOV - 3 1997

Hollister

Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048-3781

InCare HOT/ICE Cold Therapy Foot/Ankle Blanket

510(k) Summary

K973023

1. Submitter's name, Address and Contact Person

Submitter
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Contact Person
Joseph S. Tokarz
Manager, Regulatory Affairs
Ph (847)680-2849
Fax (847)918-3860

Date Summary Prepared - August 12, 1997

2. Name of Device:

InCare HOT/ICE System Foot/Ankle Blankets

3. Name of Predicate Device(s)

InCare HOT/ICE System Foot/Ankle Blankets (K931843)

4. Description of Device

Hollister Incorporated, through its InCare division, currently markets the HOT/ICE System which is intended to provide hot/cold therapy for body surfaces. The HOT/ICE System products operate by pumping heated or chilled water through a plastic blanket.

The proposed devices consist of a connector/tubing that is an integral part of the plastic blanket where warm or cold water is circulated through and is intended to be used for the delivery of hot or cold therapy to the Foot/Ankle surface of the body. Detachable hook and loop securing straps allow for more flexibility in positioning the blanket onto the Foot/Ankle.

The proposed HOT/ICE System Foot/Ankle Blanket can be used with all of the circulating pumps within the InCare HOT/ICE System and is available as a sterile product.

5. Statement of Intended Use

The InCare HOT/ICE System Foot/Ankle Blanket is intended to provided hot/cold therapy for body surfaces.

6. Statement of Technological Characteristics of the Device

The subject device is identical in intended use, size/shape and flow design to the predicate device, with the following exception, the proposed device is available with detachable

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hook and loop securing straps that hold the blanket in place and allow for more flexibility in positioning the blanket.

7. **Biocompatibility Assessment**

Material Biocompatibility: Issues of biomaterial safety or biocompatibility have been addressed based upon the biomaterial history or in separate in-vitro or in-vivo evaluations using licensed commercial reference laboratories. Each assessment was conducted based on principles and guidelines established by various governmental and standard setting organizations among these are the following:

-- ISO 10993, International Standards Organization (ISO) Standard
-- General Program Memorandum #G95-1, United States FDA Office of Device Evaluation
-- United Stated Pharmacopeia (USP)

The materials used to construct the InCare HOT/ICE Cold Therapy Foot/Ankle Blanket are considered biocompatible and appropriate for their intended use.

8. **Conclusion**

Based upon the information presented above it is concluded that the proposed InCare HOT/ICE Cold Therapy Foot/Ankle Blanket is safe and effective for it's 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

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Mr. Joseph S. Tokarz
Manager, Regulatory Affairs
Hollister, Inc.
2000 Hollister Drive
Libertyville, Illinois 60048-3781

Re: K973023
InCare HOT/ICE Cold Therapy Foot/Ankle Blanket
Regulatory Class: II
Product Code: ILO
Dated: August 11, 1997
Received: August 14, 1997

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4659. 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

b. Statements of Indications for Use

510(k) Number (if Known): _____
Device Name: InCare HOT/ICE Cold Therapy Foot/Ankle Blanket

Indications For Use:

The InCare HOT/ICE Cold Therapy Foot/Ankle Blanket is intended to provide hot/cold therapy for body surfaces.

(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 X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973023