



Hollister

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InCare HOT/ICE Cold Therapy Blankets

510(k) Summary

1. Submitter's name, Address and Contact Person

Submitter

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Contact Person

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2. Name of Device:

InCare HOT/ICE System Blankets

3. Name of Predicate Device(s)

InCare HOT/ICE System Blankets (K871962, K871963 and K833564)
ImmobilICE Support Blankets

4. Description of Device

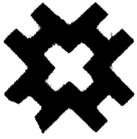
Hollister Incorporated, through its InCare division, currently markets the HOT/ICE System which is intended to provide hot/cold therapy for body surfaces. The HOT/ICE System products operate by pumping heated or chilled water through a plastic blanket.

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. The proposed HOT/ICE System blankets are intended to be used for the delivery of hot or cold therapy to various body surfaces. The devices are available in various sizes to accommodate a wide range of body surfaces and depending on the caregivers preference, with or without straps to secure the device to the patient. Hook and loop securing straps allow for more flexibility in positioning the blankets. The material used to construct the bladder has been changed to polyurethane to allow for more conformity when applying the blanket.

The proposed HOT/ICE System Blankets can be used with all of the circulating pumps within the InCare HOT/ICE System and are available in sterile and non-sterile versions.

5. Statement of Intended Use

The InCare HOT/ICE Cold Therapy Blankets are intended to provide hot/cold therapy for body surfaces.



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6. Statement of Technological Characteristics of the Device

The subject devices are identical in intended use, size/shape availability and flow design to the currently available InCare HOT/ICE Blankets (K871962, K871963 and K833564), with the following exceptions, the material used to construct the bladder has been changed to polyurethane to allow for more flexibility when applying the blanket and the blankets are available with detachable hook and loop securing straps that hold the blanket in place and allow for more flexibility in positioning the blankets.

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 States Pharmacopeia (USP)

The materials used to construct the InCare HOT/ICE Cold Therapy Blankets 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 Blankets are safe and effective for their intended use and are substantially equivalent to the predicate devices.