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## InCare HOT/ICE Cold Therapy Shoulder Blanket

### 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 Shoulder Blankets

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

InCare HOT/ICE System Shoulder 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 shoulder surface of the body. Detachable hook and loop securing straps allow for more flexibility in positioning the blanket onto the shoulder.

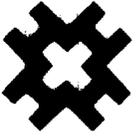
The proposed HOT/ICE System Shoulder Blanket can be used with all of the circulating pumps within the InCare HOT/ICE System and is available as a sterile product.

#### 5. Statement of Intended Use

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

#### 6. Statement of Technological Characteristics of the Device

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



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detachable 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 States Pharmacopeia (USP)

The materials used to construct the InCare HOT/ICE Cold Therapy Shoulder 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 Shoulder Blanket is safe and effective for its intended use and is substantially equivalent to the predicate device.