

K96294

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**510(k) PREMARKET NOTIFICATION SUMMARY**

**Submitter's name and address:**

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**Contact person, telephone number and fax number:**

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**Device Trade or proprietary name:**

TotalCare®

**Device common or usual name:**

AC powered hospital bed

**Device classification name:**

General Hospital and personal use devices  
80FNL  
880.5100, AC powered hospital bed

**Identification of the marketed device(s) to which equivalence is claimed:**

K922352 Advance Series, Hill-Rom, Inc.  
K925576 Burke Bariatric Treatment System, Burke Mobility Products  
K915437 Critical Care Hospital Bed, Hill-Rom, Inc.

## **Summary:**

The subject hospital bed and predicate hospital beds in this submission are substantially equivalent. The subject device has the same or similar materials, technology and performance characteristics as the predicate devices. The subject device is intended to be used as a comprehensive product ideally suited to be used in health care environments.

The product may be used in a variety of settings including, but not limited to, acute care, including critical care, step down/progressive care, medical/surgical, high acuity sub-acute care, post anesthesia care unit (PACU), and sections of the emergency department (ED). The product is capable of being used with a broad patient population as determined appropriate by the caregiver or institution. The device is intended to provide significant improvements in caregiving and a safer environment for caregiver and patient

These capabilities are achieved using manual, hydraulic and/or electric power. Various proposed accessories, and options will be available to supplement the capabilities and convenience of the product in the field. The product consists of mechanical, electromechanical, hydraulic, and electronic components. These may be selected by the caregiver or institution to customize the bed to specific patient population needs.

Performance standards for the device have not been established under Section 514 of the FD&C Act. The platform has an optional radiotranslucent surface. Testing and procedures for the surface have been implemented to assure compliance with performance standards established under 21 CFR 1020 "Performance Standard for Ionizing Radiation Emitting Products." The products shall comply with the following documents:

- UL 2601-1 (1st Edition) Medical Electrical Equipment Regulatory Standard
- CSA C22, No. 601.1 Canadian Safety Standard
- UL 1069 (4th Edition) Hospital Signaling & Nurse Call Equipment Regulatory Standard
- IEC 601-1 (Second Edition) Medical Electrical Equipment - General Requirements for Safety
- IEC 601-1-2 (First Edition) Collateral Standard - Electromagnetic Compatibility
- IEC 601-2-38 (Draft) Particular Bed Standard