JUN 3 2013

# 510K Summary

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| **Date Summary was Prepared:** | August 10, 2012 |
| **510(k) Submitted:** | Ann Waterhouse, RAC<br>Director, Regulatory Affairs<br>1069 State Route 46 East<br>Batesville, IN 47006<br>(812) 931-2634<br>(812) 934-1675 (facsimile) |
| **Device Trade Name:** | Hill-Rom TotalCare® Modular Therapy (Bed) System |
| **Device Common Name:** | Bed, Flotation Therapy, powered Bed, AC powered adjustable hospital bed, Hydraulic adjustable hospital bed |
| **Device Product Codes and Classification:** | IOQ, Class II<br>Bed, floatation therapy, powered (21 CFR 890.5071)<br>FNL, Class II<br>Bed, AC powered adjustable hospital bed (21 CFR 880.5100)<br>FNK, Class II<br>Bed, Hydraulic adjustable hospital bed (21 CFR 880.5110) |
| **Predicate Devices:** | Stryker iBed Wireless with iBed Awareness (K103536)<br>Hill-Rom TotalCare (K962942)<br>Hill-Rom TotalCare Modular Therapy System (K970636)<br>Hill-Rom Rumors DynamicAir (K972111) |
| **Device Description:** | The TotalCare® Modular Therapy (Bed) System is a control unit (GUI) and frame which can house several therapeutic surfaces. The system can articulate to provide different positions for treatment, sleeping, up-in-bed, and other physician recommended positions. The Graphical Caregiver Interface/ Graphical User Interface can be set for alarms such as patient egress and head-of-bed angle. |
| **Statement of Intended Use:** | The TotalCare® Modular Therapy (Bed) System is intended as a patient support system. It is to be used in health care environments such as, 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 TotalCare® Bed System is capable of being used with a broad patient population as determined appropriate by the caregiver or institution.<br>The TotalCare® Bed System, dependent upon model, is capable of supporting patient populations up to 500 lbs. |

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| **Indications for Use:** | The TotalCare® Bed System is intended to be used to treat or prevent pulmonary or other complications associated with immobility; to treat or prevent pressure ulcers; or for any other use where medical benefits may be derived from either Continuous Lateral Rotation Therapy or Percussion/Vibration Therapy. The TotalCare® Bed System is intended to provide a patient support to be used in health care environments. The TotalCare® Bed System 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 TotalCare® Bed System is capable of being used with a broad patient population as determined appropriate by the caregiver or institution.<br>The TotalCare® Bed System, dependent upon model, is capable of supporting patient populations up to 500 lbs. |
| **Non-Clinical Performance Summary:** | Hill-Rom has verified and validated that the TotalCare® Modular Therapy Bed System meets functional, performance, safety and efficacy specifications and requirements in compliance with the following international standards:<br><br>IEC 60601-I, Medical Equipment - part 1: General Requirements for Safety,1990+AI ;1993+A2 1995+AI3;I1996<br><br>IEC 60601-1-2; 2001Medical Electrical Equipment Part 1-2 General Requirements for Basic Safety and Essential Performance-Collateral Standard: Electromagnetic Compatibility Requirements and Tests<br><br>IEC 60601-1-4; 1996-A 1; 1999 Medical electrical Equipment, Part 1: General requirements for safety-4: Collateral standard: Programmable electrical medical systems<br><br>IEC 60601-2-38 Particular requirements for the safety of Electrically Operated hospital beds. |
| **Supporting Data:** | Clinical testing was not required for determination of substantial equivalence. A literature review was compiled of articles related to safe patient handling and benefits of therapy surfaces and beds of this type for patients experiencing prolonged immobility. Those articles can be found in the Clinical articles section of the 510(k). |
| **Conclusion:** | The data herein supports this device, Hill-Rom TotalCare® Modular Therapy (Bed) System as safe, effective, and performing as well as or better than the predicate devices, and therefore is substantially equivalent. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 3, 2013

Ms. Ann Waterhouse
Director of Regulatory Affairs
Hill-Rom
1069 Sate Route46 East
BATESVILLE, IN 47006-9167

Re: K122473
Trade/Device Name: TotalCare®™ Modular Therapy System
Regulation Number: 21 CFR 890.5170
Regulation Name: Powered Flotation Therapy Bed
Regulatory Class: II
Product Code: IOQ
Dated: May 10, 2013
Received: May 21, 2013

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, DDS, MA

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S
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Date: 2013.06.03 15:18:41 -04'00'

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

**510(k) Number (if known):** K122473

**Device Name:** Hill-Rom TotalCare®™ Modular Therapy System

**Indications for Use:**

The TotalCare® Bed System is intended to be used to treat or prevent pulmonary or other complications associated with immobility; to treat or prevent pressure ulcers; or for any other use where medical benefits may be derived from either Continuous Lateral Rotation Therapy or Percussion/Vibration Therapy. The TotalCare® Bed System is intended to provide a patient support to be used in health care environments. The TotalCare® Bed System 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 TotalCare® Bed System is capable of being used with a broad patient population as determined appropriate by the caregiver or institution.

The TotalCare® Bed System, dependent upon model, is capable of supporting patient populations up to 500 lbs.

| Prescription Use _____ | Over-The-Counter Use X |
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| (Part 21 CFR 801 Subpart D) | (21 CFR 801 Subpart C) |

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122473