K112502

510(k) Summary
Hill-Rom Procedural Stretcher with Intellidrive®

SEP 19 2011

Device Owner:
Hill-Rom, Inc.
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Date Summary Prepared: 6/30/11

Device Names:
Trade Name: Hill-Rom Procedural Stretcher with Intellidrive®
Common Name: Powered stretcher
Classification Name: Stretcher, Wheeled, Powered, (21 CFR 890.3690, Product Code INK)

Regulatory Class: Class II

Predicate Devices: Stryker Powered Wheeled Stretcher, #K022309

Device Description: The Hill-Rom Procedural Stretcher product is a movable, caster-mounted stretcher. The product has side rails, supports for fluid infusion equipment, and a scale for weighing patients. A twin-hydraulic cylinder lift system provides support, height adjustment and Trendelenburg features for the patient surface. The stretcher is available with an optional that consists of the addition of a battery-powered drive mechanism which is integrated into the stretcher platform provides propulsion of the platform along the floor with minimal force applied by the caregiver. The powered drive mechanism is only controllable by the caregiver and not the patient. The Intellidrive® option aids in the transportation of patients by providing healthcare personnel with the ability to more easily move and maneuver the stretcher.

The Hill-Rom Procedural Stretcher with Intellidrive® meets the requirements of IEC 60601-1 (Electrical Safety) and IEC 60601-1-2 (Electromagnetic Compatibility). The device carries the ETL marking to UL60601-1 and CAN/CSA C22.2 NO, 601.1-M90.

Intended Use: The Hill-Rom Procedural Stretcher with Intellidrive® is intended to assist caregivers in the treatment and transportation of patients in all areas of hospitals, surgical centers, and other patient care facilities. The Intellidrive® Transport System is a permanently attached powered drive that is assembled into the existing Procedural Stretcher model. This feature lets the caregiver move the stretcher forward or reverse with very little applied force. The caregiver operates the system through the transport handles.

Similarities and Differences:
The Hill-Rom Procedural Stretcher with Intellidrive® is substantially equivalent in function and intended use to the Stryker® Powered Wheeled Stretcher. Each is intended to provide assistance to caregivers in the treatment and transportation of patients in healthcare facilities.

The predicate device is a Class II device, classified at 21 C.F.R. and 890.3690, Stretcher, Wheeled, Powered, Product Code INK. This is the same classification as the device being submitted.

As with the predicate device, this product is a movable, caster-mounted stretcher. Both products have side rails, supports for fluid infusion equipment, and a scale for weighing patients. A twin-hydraulic cylinder lift system provides support, height adjustment and Trendelenburg features for the patient surface. In both products, the addition of a powered transport mechanism to a normal transport stretcher enables the caregiver to move the stretcher with very little applied force.

Hazards for the product were identified in a systematic manner. A list of known or foreseeable hazards associated with the product both in normal and fault conditions was compiled and evaluated. A comprehensive review of field complaints, MDR's and recalls from similar Hill-Rom products and the predicate device was conducted and included in the hazard identification process. This review was conducted by a cross-functional team composed of members from Engineering, Quality, Regulatory Affairs, and Clinical.

A verification and validation plan has been developed that defines the testing parameters that ensure that the product meets its design requirements and that the hazards that were identified were eliminated by design features or that the occurrence rate is a low as reasonably possible. The testing was conducted on both a system level, with the system being the entire stretcher, and a module level, with the module being the Intellidrive mechanism. Safety and performance characteristics of the device were identified via customer needs and functional requirements of the device. The characteristics were converted into requirements that were verified and validated successfully. The product also successfully meets the following voluntary standards:

Medical Electrical Equipment: Part 1: General Requirements for Safety – UL 60601-1 (1st Ed., 25-Apr-03, Rev 26-Apr-06);

Medical Electrical Equipment: Part 1: General Requirements for Safety – General Instruction No. 1 - CAN/CSA C22.2 601.1-M90 (1st Ed., Nov-90, R2005) + Supplement No. 1-94 (C22.2 No. 601.1S1-94, Feb-94, R1999) + Amendment 2:1998 (Feb-98, R2006) + Update No. 2 (Nov-03, R2005);

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General);

IEC 60601-1-4:2000 Consol. Ed. 1.1, Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1. (General)

IEC 60601-2-38 1996/Amendment 1:1999, Medical electrical equipment - Part 2-38: Particular requirements for the safety of electrically operated hospital beds. (General Plastic Surgery/General Hospital)

IEC 60601-1-2 Edition 3:2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. (General)

Based on the information from stretcher test results and a review of the predicate device's functions and features, any differences described between the Hill-Rom Procedural Stretcher with Intellidrive® and that of the predicate device do not raise new issues of safety or effectiveness. The intended use, basic technology, and performance characteristics of the system are the same.

A summary table is included on the following page that compares the new device and the predicate device.

Prepared by:
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Hill-Rom Company

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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SEP 19 2011

Re: K112502
Trade/Device Name: Hill-Rom® Procedural Stretcher with Intellidrive®
Regulation Number: 21 CFR 890.3690
Regulation Name: Powered wheeled stretcher
Regulatory Class: II
Product Code: INK
Dated: September 15, 2011
Received: September 16, 2011

Dear Ms. Wilkerson:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD

Device Name: Hill-Rom® Procedural Stretcher with Intellidrive®

Indications for Use:

The Hill-Rom® Procedural Stretcher with Intellidrive® is intended to assist caregivers in the treatment and transportation of patients in all areas of hospitals, surgical centers, and other patient care facilities. The Intellidrive™ Transport System is permanently attached powered drive that is assembled into the existing Procedural Stretcher model. This feature lets the caregiver move the stretcher forward or reverse with very little applied force. The caregiver operates the system through the transport handles.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112502