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**510(k) PREMARKET NOTIFICATION SUMMARY**

**Submitter's name and address:**

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**Device Trade or proprietary name:**

To be determined

**Device common or usual name:**

Ambulatory care procedural stretcher

**Device classification name:**

Wheeled Stretcher

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

Stryker "Synergy Series" Stretchers

**Description:**

A wheeled stretcher is a device consisting of a platform mounted on a wheeled frame that is designed to transport patients in a horizontal position. The device may have side rails, supports for fluid infusion equipment, and patient securement straps.

) There is some variation in the construction and design of the stretchers but the variations do not significantly affect the safety or efficacy of the stretchers. As with the predicate stretcher, the stretcher which is the subject of this submission will be a movable, caster mounted design with variable height and trendelenburg features. In addition, as with predicate stretcher, the variable height top surface of the stretcher will utilize a twin tower design with two hydraulic cylinders mounted in a vertical orientation near the ends of the base. The Stretcher is designed to meet U.L. and I.E.C. stability requirements.

The subject stretcher and predicate are intended to be used with the general population to transport patients and to allow for patient care before, during, and after transport. The stretchers may be used in or for various patient care facilities and departments including, but not limited to, ED, transport, PACU, ambulatory surgery, long term care and home care. When fitted with the optional radiolucent surface, the stretcher may be used for acquisition of radiographic images.

The labels and in-service manual provide information which describes the device, its intended uses, and the directions for operation enabling proper and safe use the product.

) Performance standards applicable to wheeled stretchers have not been established under Section 514 of the FD&C Act.

Significant safety and performance characteristics are tested to assure compliance with specifications. Upon completion the test results become part of the device master record as required under the GMP, 21 CFR 820. A complete review of hazards associated with the product was performed. This review included research of complaint, MDR and trade association databases. In addition, identification of other potential structural and performance hazards was completed by engineering. Testing has been developed to assure that these hazards have been eliminated or the severity or probability of occurrence minimized.

The stretcher platform has an optional radiolucent 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 device will also comply with the following voluntary standards.

IEC 601-1	Medical electrical equipment; Part 1: General requirements for safety 2nd edition, 1988.
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IEC 601-2-38	Medical electrical equipment; Part 2: Particular requirements for the safety of electrical, energized, and non-energized hospital beds.
UL 2601-1	First edition of the standard for medical electrical equipment, Part 1: General requirements for safety.
CAN/CSA-C22.2	No. 601.1-M90, Medical electrical equipment; Part 1: General requirements for safety.
IEC 601-1-2	Electromagnetic Compatibility Requirements

The subject stretcher and predicate stretcher in this submission are substantially equivalent.