DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 8 2002

Stryker Corporation
c/o King and Spalding
Lynette Gabriel
1730 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-4706

Re: K022309
Trade/Device Name: Stryker Powered Wheeled Stretcher
Regulation Number: 890.5150
Regulation Name: Powered patient transport
Regulatory Class: Class II
Product Code: INK
Dated: August 13, 2002
Received: August 13, 2002

Dear Ms. Gabriel:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K022309

Device Name: Stryker Powered Wheeled Stretcher

Indications For Use:

The Stryker Powered Wheeled Stretcher is an electromechanical stretcher that provides a method of transporting patients within healthcare facilities. The stretcher may be used for minor procedures and short-term stay, typical of existing stretcher applications.

The drive-assist Big Wheel provides the healthcare caregiver greater maneuverability in steering and moving the stretcher with significantly less force.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The- Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milleson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022309

K022309

stryker Medical

6300 Sprinkle Road
Kalamazoo, MI 49001-9799
www.stykermedical.com
Phone (616) 329-2100
Fax (616) 329-2311
(800) 669-4968

Device Name:

Trade Name:	Stryker Powered Wheeled Stretcher
Common Name:	Powered Wheeled Stretcher
Classification Name:	Powered Patient Transport, 21 CFR 890.5150, Class II

Device Sponsor:

Manufacturer:	Stryker Corporation Stryker Medical 6300 S. Sprinkle Road Kalamazoo, MI 49001 Registration No.: 1831750

Regulatory Class: Class II

Identification Of The Marketed Device(s) To Which Equivalence Is Claimed

Stryker Powered Wheel Stretcher (510k#: K942948)

Intended Use Statement:

The Stryker Powered Wheeled Stretcher is a powered patient transport device with a motorized drive wheel to aid the caregiver in maneuvering the stretcher while transporting patients within healthcare facilities.

Summary:
The new stretcher is a drive-assisted version of the former Stryker Powered Wheeled Stretcher. This stretcher is a motorized device to be used to transport patients to various areas within the healthcare facility and may contain siderails, supports for fluid infusion equipment, and patient securement straps.

The predicate device has patient controls that allow the patient to adjust the stretcher to their comfort level. The stretcher height can be increased or decreased; the head and knee section can be raised or lowered. This stretcher doesn't have a fifth wheel to aid the maneuverability of the stretcher. The power is only for stretcher function and patient controls.

The stretcher, which is the subject of this submission, will have a motorized drive-assist fifth wheel that will assist the caregiver in maneuvering the stretcher. Only the caregiver, not the patient, can control this drive wheel and stretcher height. This stretcher will not have any patient controls to adjust patient positioning.

As with the predicate device, the stretcher of this submission will be a movable, caster mounted design with variable height and Trendelenberg features. In addition, as with the predicate stretcher, the lift system provides both support and height adjustment for the patient surface through the use of hydraulic jacks. The stretcher is designed to meet UL and IEC stability requirements.

The subject stretcher and predicate stretcher are intended to be used in any clinical environment where patient care is being administered. Healthcare facilities typically use stretchers as

treatment, recovering or transporting surfaces. Clinical activities to include, but not limited to examination, surgery, recovery, therapy, and transport. When fitted with the optional radiolucent surface, the stretcher may be use for the acquisition of radiographic images.

The labels and Operations Manual provide information that describes the stretcher, its intended use, and the directions for properly operating the stretcher safely.

No performance standards or special controls applicable to powered patient transport devices have been established under sections 513 or 514 of the FD & C Act.

Significant safety and performance characteristics are tested to ensure compliance with specifications. After testing is complete, the test reports become part of the Device Master Record as required by 21 CFR 820 Quality System Regulation.

A review of risks and hazards of the product was conducted. This included complaints, recalls, and medical device reports analyses. Also, a review was also conducted to identify other potential structural and performance hazards by a cross-functional team, which included representatives from, but not limited to, Engineering, Quality, and Regulatory Affairs. A verification and validation plan has been developed to ensure these hazards have been eliminated or the severity or occurrence minimized.

The stretcher will also comply with the following voluntary standards:

IEC 601-1-1	Medical Electrical Equipment - Part 1: General Requirements For Safety 1: Safety Requirements For Medical Electrical Systems.
IEC 601-1-2	M Medical Electrical Equipment - Part 1: General Requirements For Safety 2: Electromagnetic Capability - Requirements and Tests.
UL 2601-1	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.

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

By: Catherine McFriday
Catherine Friday
Regulatory Affairs/Quality System Engineer

Dated: July 15, 2002