510(k) Summary for The Hausted® POWERTRAN™ Series Stretcher

SEP - 9 2004

K041924

510(k) SUMMARY PERTAINING TO THE SAFETY AND EFFECTIVENESS OF The Hausted® POWERTRAN™ Series Stretcher

Submitter Information:
Robert H. McCall
Senior Regulatory Affairs Specialist
2720 Gunter Park Drive East
Montgomery, Alabama, 36109
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334-271-3579

Date Summary Prepared: July 14, 2004

Name of the device:	The Hausted® POWERTRAN™ Series Stretcher
Common or usual name of the device:	Powered Patient Transport
Classification name of the device:	Powered Patient Transport

Predicate Device: Stryker ZOOM® Motorized Stretchers

Device Description: The Hausted® POWERTRAN™ Series Stretcher is a powered patient transport. This device is a motorized device intended for medical purposes to assist in the transfer of patients to and from the bath, beds, chairs, treatment modalities, and transport vehicles. The FDA has classified the device as a Class II device. The FDA has classified powered patient transports as a Class II device.

The Hausted® POWERTRAN™ Series Stretcher is designed to assure compliance with IEC 60601-1 (Electrical Safety) and IEC 60601-1-2 (Electromagnetic Compatibility). The device will also carry the ETL (to UL 2601-1) and cETL (to CAN/CSA C22.2 No. 601.1-M90) markings. Electrical testing will be certified by the accredited testing facility shown at the end of this certification. Software testing is being certified by STERIS as the manufacturer.

Intended Use: This device is a motorized device intended for medical purposes to assist in the transfer of patients to and from the bath, beds, chairs, treatment modalities, and transport vehicles. The FDA has classified the device as a Class II device.

Device Comparison: The Hausted® POWERTRAN™ Series Stretcher is substantially equivalent to the ZOOM® Motorized Stretchers and the Stryker Powered Wheeled Stretcher in function and intended use.

The Hausted® POWERTRAN™ Series Stretcher is substantially equivalent to the ZOOM® Motorized Stretchers and the Stryker Powered Wheeled Stretcher in function and intended use. The minor differences described in the submission between The Hausted® POWERTRAN™ Series Stretcher and that of the predicate devices does not raise any new issues of safety or effectiveness.

The intended use, basic technology, and performance characteristics of the systems are the same. The device does not contact the patient, so biocompatibility is not a concern.

The subject stretcher is intended to be used in any clinical environment where patient care is administered. Health facilities ordinarily use stretchers for patient treatment, recovery and for transportation to and from treatment modalities, i.e., physical therapy, diagnostic radiography, etc.

The labels and labeling (Operator's and Maintenance Manuals) provide information for the safe operation by the caregiver/user and the intended operation features.

No performance standards or special controls have been promulgated for powered patient transport devices under sections 513 and 514 of the FD& C Act.

Safety Testing and performance characteristics have been conducted and successfully completed in order to ensure compliance with specifications. These reports are maintained as required by 21 CFR 820, Quality Systems Regulations.

An assessment of known and reasonable hazards has been conducted to ensure that any risk associated with the device as of the date of product release is as low as reasonably possible. Design controls have been applied in accordance with FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001.

Design review has been conducted by a cross-functional team, including but not limited to regulatory, quality, engineering, technical writing and manufacturing.

The stretcher will comply with the following voluntary standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety,
  1988 (General), Amendment 1, 1991-11, Amendment 2, 1995-03

- IEC 60601-1-2, (First Edition, 1993-04), Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests (General)

- UL 2601-1
  (2nd Ed.) Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety

- CAN/CSA C22.2 No. 601.1-M90 Standard for Medical Electrical Equipment

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

Prepared by:

Robert H. McCall
Senior Regulatory Affairs Specialist
STERIS-Montgomery Operations

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2004

Mr. Robert H. McCall, RAC
Senior Regulatory Affairs Specialist
STERIS Corporation
2720 Gunter Park Drive East
Montgomery, Alabama 36109-0509

Re: K041924
Trade/Device Name: The Hausted® POWERTRAN™ Series Stretcher
Regulation Number: 21 CFR 890.3690
Regulation Name: Powered Wheeled Stretcher
Regulatory Class: II
Product Code: INK
Dated: August 10, 2004
Received: August 12, 2004

Dear Mr. McCall:

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.

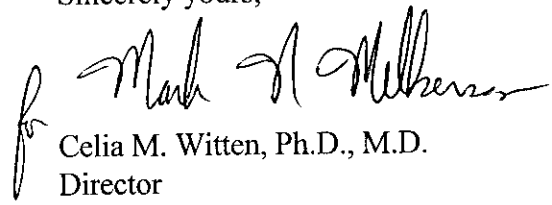
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Indications for Use

510(k) Number (if known): K041924

Device Name: The Hausted® POWERTRAN™ Series Stretcher

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

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041924