FEB 1 1 2005

K 050264

510(k) SUMMARY

STEALTH PRODUCTS
POWERED SEATING SYSTEM FOR
POWERED WHEELCHAIRS

Submitter

Stealth Products, Inc.
103 John Kelly Drive
P.O. Box 468
Burnet, Texas 78611
Phone: (800) 965-9229
Fax: (800) 806-1225

Contact Person

Edward A. Kroll
President
Spectre Solutions
5905 Fawn Lane
Cleveland, Ohio 44141
Phone: (440) 546-9810
Fax: (440) 546-9124

Date Prepared: February 1, 2005

Name of Device

Stealth Products Powered Seating System for Power Wheelchairs

Common or Usual Name

Power Wheelchair Seating System

Classification Name

Wheelchair, Powered

Predicate Devices

Invacare Corporations' Model 2G Tilt/Recline Seating System for Power Wheelchairs (K991119) and Accelerated Rehab Designs, Inc. Model T-2000 Power Tilt Seating System (K992804).

Intended Use

The intended use of the Stealth Products Powered Seating System is to provide pressure relief to persons confined to a wheelchair, by providing a method of tilting and reclining the wheelchair seat and back.

Device Description

The Stealth Products Powered Seating System for power wheelchairs is a battery powered, motorized seating system, designed for use with power wheelchairs. It's intended function and use is to provide pressure relief to power wheelchair users, by providing a means of tilting and reclining the seat and back.

The system consists primarily of a main frame assembly, a system mounting plate, linear actuators and a toggle switch assembly. The main frame assembly supports the patient during use of the seating system. The system mounting plate is the interface between the Stealth Seating System and the wheelchair. The linear actuator provides the motion needed to position the system, and the toggle switch assembly is the means by which the tilt/recline functions are activated.

The Stealth Powered Seating System is designed to adapt to wheelchairs with round, square, or rectangular frames. Minimum frame requirements are 1 ½" diameter x .09 wall for round frames and a 1" mounting surface x .09 wall for square and rectangular frames.

Substantial Equivalence

The Stealth Products Powered Seating System is substantially equivalent to Invacare Corporations' Model 2G Tilt/Recline Seating System for Power Wheelchairs (K991119) and the Accelerated Rehab Designs, Inc. Model T-2000 Power Tilt Seating System (K992804).

Performance Data

Stealth Products has conducted performance and functional testing on the Stealth Products Powered Seating System. In all cases, the Stealth System passed its' performance requirements and met specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

Stealth Products, Inc.
C/o Edward A. Kroll
President, Representative Consultant
Spectre Solutions
5905 Fawn Lane
Cleveland, Ohio 44141

Re: K050264
Trade/Device Name: Stealth Products Powered Seating System for Power Wheelchairs
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: February 2, 2005
Received: February 4, 2005

Dear Mr. Kroll:

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 (240) 276-0120 . 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/industry/support/index.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

Indications for Use

510(k) Number (if known): TBD

Device Name: Stealth Products Powered Seating System for Power Wheelchairs

Indications for Use:

The intended function and use of the Stealth Products Powered Seating System for Power Wheelchairs is to provide comfort and pressure relief to power wheelchair users, by providing a method of tilting and reclining the seat and back.

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

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

Mark N Milhouse

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

10(k) Number K050264