K994083

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APR - 4 2001

510(k) SUMMARY

Stannah Power Chair Ltd.
Model 201 Power Chair

Submitters Name, Address, Telephone Number, Contact Person and Date Prepared.

Stannah Power Chairs Ltd.
Watt Close
East Portway Ind. Estate
Andover
Hampshire
SP10 3SD
England

Contact Person: Charles Edgell
Director Stannah Power Chairs Ltd

Date Prepared: December 1999

Name of Device and Name / Address of Sponsor

Stannah Power Chair Model 201

Stannah Power Chairs Ltd.
Watt Close
East Portway Ind. Estate
Andover
Hampshire
SP10 3SD
England

Common or Usual Name

Powered Wheelchair

Classification Name

Wheelchair, Powered

Predicative Devices

Pride Health Care "Jazzy" Powered Wheelchair
(510(k) # K 945936 date 05/28/94)

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Intended Use

The Stannah power Chair is intended as a device to provide personal transport for a person with walking difficulties. It is specifically designed to for indoor use in a domestic type environment.

Technological Characteristics and Substantial Equivalence

Device Description:

The Power Chair is a powered wheelchair based around a high quality office chair. Attached to the chair is a proprietary controller unit, which can be mounted on either side of the seat. The motion is operated by the user hand via a joystick. The attachment method allows the controller to be positioned further forward or backwards relative to the chair for comfort and convenience of the user.
The chair is attached to a base assembly containing the drive motors, drive wheels, castor wheels and batteries, by a Gas Strut (anti-rotate) which enables the chair to be raised or lowered within set limits. Operation may be either manual, using a hand lever, or with a powered version option, via a separate control on the controller unit. The powered height adjustment can not be made while the power chair is driving in any direction.
The Base is a profiled and of folded sheet steel fabrication, to which the two drive motor/gearboxes, two drive wheels, five castor wheels and a footrest assembly are mounted directly.

Substantial Equivalence

The Stannah Power Chair Model 201 is substantially equivalent to other devices of comparable type that are currently being legally marketed within the United States of America. The comparable device quoted and compared is the Pride Health Care "Jazzy" powered wheel chair, (510(k) # K 945936 date 05/28/94).
Each of the products are battery powered, twin motor gearbox driven, mid wheel drive powered wheelchairs with the same intended function and use, which is to provide mobility to persons with walking difficulties, that have the capability of operating a powered wheelchair. They also offer excellent maneuverability due to their drive geometry. They are constructed of the same basic materials and have the same basic operational principles.

Performance Data

As required by the FDA's July 26th, 1995, draft publication entitled "Guidance Document for the Preparation of Pre-Market Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles". The Stannah Power Chair conforms to appropriate sections of BS/ISO Powered Wheelchair Standard #ISO 7176 parts 1-16.
The Power Chair was also tested in accordance with the ISO EMC Draft Standard 7176-14, (titled "Draft ISO EMC Group Proposal: Electromagnetic Compatibility Addition" dated April 3rd, 1995) for Powered Wheelchairs and Scooters. In all instances, the Stannah Power Chair Model 201 met the required performance criteria and functioned as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2001

Mr. Charles Edgell
Commercial Director
Stannah Power Chairs LTD.
Watt Close
East Portway Ind. Estate
Andover, Hampshire SP10 3SD
England

Re: K994083
Trade Name: Stannah Power Chair, Model 201
Regulatory Class: II
Product Code: IPL
Dated: February 8, 2001
Received: February 8, 2001

Dear Mr. Edgell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/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 (If known): **K994083**

Device Name: **Stannah Power Chair Model 201**

Indications for Use:

The Stannah Power Chair is intended as a device to provide personal transport for a person with walking difficulties. It is specifically designed for indoor use in a domestic type environment.

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

510(k) Number K994083