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K993413

1 of 3

510(k) SUMMARY

INVACARE CORPORATION'S
510(k) PREMARKET NOTIFICATION
STORM SERIES, POWER 9000 SERIES AND POWER TIGER
POWER WHEELCHAIRS WITH GYROSCOPE CONTROL

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6595
Facsimile: (440) 365-4558

Contact Person: Edward A. Kroll
Director, TQM and Regulatory Affairs

Date Prepared: October 7, 1999

Name of Device and Name/Address of Sponsor: Storm Series, Power 9000 Series and Power Tiger power wheelchairs with gyroscope control

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6595
Facsimile: (440) 365-4558

Common or Usual Name
Power Wheelchair

Classification Name
Wheelchair, Powered

Predicate Devices
Products which are substantially equivalent to the Models Storm, Power 9000 and Power Tiger with gyroscope control are; the Invacare Storm Power wheelchair (K940051), the Invacare Power 9000 Power Wheelchair (K900565) and the Invacare Power Tiger Power Wheelchair (K930676).

Intended Use
The intended use of the Storm Series, Power 9000 Series and Power Tiger power wheelchairs with gyroscope control is to provide mobility to persons limited to a seated position.

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Technological Characteristics and Substantial Equivalence

Device Description

The Invacare Storm Series, Invacare Power 9000 Series, Power Tiger power wheelchairs with gyroscope control are battery powered, motorized mobility vehicles. Their intended function and use is to provide mobility and transportation to physically challenged persons that may be restricted to a seated position.

The various models differ somewhat in design, drive mechanisms, styling, aesthetics and mechanical components. The primary difference between the Power 9000 Series and the Storm Series wheelchairs is in the wheelchair frame style. Where the Power 9000 is a cross brace type folding frame wheelchair, the Storm is a rigid frame non-folding type wheelchair. Additionally, the Power 9000 Series wheelchairs are a basic, economical, more traditional type wheelchair whereas the Storm Series wheelchairs, are designed to have a more sporty, aesthetic appeal.

The gyroscope control feature is an angular rate sensor that measures power wheelchair speed and turning (rotational velocity), and compensates by changing wheel speed to correct for differences. The intended function of this feature is provide a more accurate response to wheelchair joystick user commands, thereby providing a more consistent response of the wheelchair drive wheels.

Substantial Equivalence

Products which are substantially equivalent to the Models Storm, Power 9000 and Power Tiger with gyroscope control Invacare Storm Power wheelchair (K940051), the Invacare Power 9000 Power Wheelchair (K900565) and the Invacare Power Tiger Power Wheelchair (K930676).

PERFORMANCE DATA

The Invacare Models Storm, Power 9000 and Power Tiger with Gyroscope Control meet the applicable requirements specified in the Rehabilitation Engineering Society of North America (RESNA) Standard ANSI/RESNA WC/14 (1991) and ISO Standard ISO 7176: 1993 (E) "ISO Standard, Wheelchairs - Requirements and Test Methods for the Power and Control Systems of Electric Wheelchairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 5 1999

Mr. Edward A. Kroll
Director, TQM and Regulatory Affairs
INVACARE Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036-2125

Re: K993413
Trade Name: Storm Series, Power 9000 Series and Power Tiger with Gyroscope Control
Regulatory Class: II
Product Code: ITI
Dated: October 7, 1999
Received: October 12, 1999

Dear Mr. Kroll:

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,

Neil R.P. Ogden for

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): *TBD*

Device Name: *Invacare Power Wheelchairs with Gyroscope Controller*

Indications For Use: *Its intended use is to provide mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair.*

NRO for

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993413

(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** X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)