K023589

1 of 2

510(k) SUMMARY

NOV 19 2002

Invacare Corporation's
Model Storm TDX Power Wheelchair

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

Invacare Corporation
One Invacare Way
PO Box 4028
Elyria, Ohio 44036
Phone: (440) 329-6356
Facsimile: (440) 365-4558

Contact Person: Rae Ann Farrow
Manager, Regulatory Compliance

Date Prepared: October 24, 2002

Name of Device and Name/Address of Sponsor

Model Storm TDX Power Wheelchair

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036-2028
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Common or Usual Name
Power Wheelchair

Classification Name
Wheelchair, Powered

Predicate Devices
Invacare Corporations' Action Arrow Front Wheel Drive Power Wheelchairs (K991168 June 25, 1999), Xterra GT Power Wheelchair (K012909, 10/24/2001) and Permobil's Chairman Front Wheel Drive Power Wheelchair (K960951, April 4, 1997).

Intended Use
The intended use of the Invacare Model Storm TDX Power Wheelchair is to provide mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Invacare Storm TDX power wheelchair is a battery powered, motor driven device with the intended function and use of providing mobility to those persons limited to a sitting position that have the capability of operating a power wheelchair. It is a rigid or "non- folding" type power wheelchair, with mid wheel drive capability.

Mid wheel drive means that the drive wheels are located near the center of the wheelchair as opposed to the rear of the wheelchair. Mounting the drive wheels more toward the center of the wheelchair, results in a chair that is easier to maneuver than the traditional rear wheel drive wheelchair.

The Invacare Storm TDX wheelchair is powered by two 12 VDC batteries. Access to the batteries is gained from underneath the chair. The need to charge the batteries will vary, depending on the type/model of the individual chair selected, and the use of the chair. The upholstery is fabricated from **U240 Nylon. This material meets California 116 and 117 and Boston Fire Department BFD-1 specifications for fire retardancy.**

B. Substantial Equivalence

Products which are substantially equivalent to these devices are **Invacare Corporations' Action Arrow Front Wheel Drive Power Wheelchairs (K991168, June 25, 1999), Invacare's Model Xterra GT Power Wheelchair (K012909, 10/24/2001), and Permobil's Chairman Front Wheel Drive Power Wheelchair (K960951, April 4, 1997).**

PERFORMANCE DATA

As required by FDA's July 26, 1995, draft publication entitled "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three- Wheeled Vehicles", the Invacare Storm TDX Power Wheelchair was tested in accordance with ISO EMC Draft Standard 7176-14 (Titled "Draft ISO EMC Group Proposal: Electromagnetic Compatibility Addition" And Dated April 3, 1995) for powered wheelchairs and motorized scooters. In all instances, the Invacare Storm TDX Power Wheelchair 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

NOV 1 9 2002

Invacare Corporation
Rae Ann Farrow
Manager, Regulatory Compliance
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036-2125

Re: K023589
Trade/Device Name: Model Storm TDX Power Wheelchair
Regulation Number: 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: October 24, 2002
Received: October 25, 2002

Dear Ms. Farrow:

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 (if known): *TBD*

Device Name: *Invacare's Model Storm TDX Power Wheelchair*

Indications For Use:

The intended use of the Invacare Model Storm TDX Power Wheelchair is to provide mobility to persons limited to a sitting position.

(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)

for Mark N Melkerson

(Optional Format 1-2-96)

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and Ne[illegible]gical Devices

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