510(k) SUMMARY
PDG PRODUCT DESIGN GROUP, INC.
MODELS FUZE T20 AND T50
MANUAL WHEELCHAIRS

JAN 17 2007

Submitter

PDG Product Design Group, Inc.
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Contact Person

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Date Prepared: December 8, 2006

Name of Device

Fuze T20 and T50 Manual Wheelchairs

Common or Usual Name

Manual Wheelchair

Classification Name

Wheelchair, Mechanical

Predicate Devices

Invacare Corporations' Action AT II Manual Wheelchair (K989447)

Intended Use

The intended use of the PDG Models Fuze T20 and T50 manual wheelchairs is to provide mobility to persons that may be limited to a seated position.

Device Description

The PDG Models Fuze T20 and T50 wheelchairs are manually operated, self propelled mechanical wheelchairs. Their intended function and use is to provide mobility to persons that may be limited to a seated position. They may also be used as attendant propelled transport devices in a health care environment such as a hospital, nursing home or extended care facility.

Both wheelchairs include a tilt mechanism which allows the upper frame of the wheelchair to be tilted. This feature is used to provide pressure relief as well as comfort to those users who may be confined to the wheelchair for extended periods of time. The tilt mechanism can also serve as an attendant aid in those situations where a patient needs to be tilted for attendant access.

Substantial Equivalence

The PDG Models Fuze T20 and T50 manual wheelchairs are substantially equivalent to Invacare Corporations' AT II Manual Wheelchair (K989447)

Performance Data

The Fuze T50 and Fuze T20 are designed to meet both the ISO 7176 - Determination of Static Stability as well as Static, Impact and Fatigue Strength; and the ANSI/RESNA WC – 19 Motor Vehicle Transportation Crash Test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

PDG Product Design Group, Inc.
% Mr. Edward A. Kroll
President, Spectre Solutions, Inc.
and Representative Consultant
5905 Fawn Lane
Cleveland, Ohio 44141

JAN 17 2007

Re: K063736
Trade/Device Name: Fuze T20 and T50 Manual Wheelchairs
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: December 12, 2006
Received: December 22, 2006

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): _____

Device Name: Fuze T20 and T50 Mechanical Wheelchairs

Indications for Use:

To provide mobility to persons limited to a seated position.

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

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

510(k) Number K063736