

K080385

Cruiser PP5500 Challenger Powered Wheelchair
510(K) Notification

510(K) SUMMARY

MAY 13 2008

Submitter's Name: E1 Enterprises Inc / Tuffcare
1290 S. W. 30th Ave.
Pompano Beach, FL 33069
(800)548-6596

Date Summary Prepared: 1/29/2008

Device Name:
Proprietary name: Cruiser PP5500 Challenger Power Wheelchair.
Common or usual name: Power Chair.
Classification name: Powered Wheelchair, Class II, 21 CFR890.3860

Legal Marketed Device for Substantial Equivalence Comparison:
Pronto M51 powered wheelchair submitted by Invacare Corp. and cleared for marketing under 510(k) #K021680.

Description of the Device:
The Tuffcare Cruiser P5500 Challenger powered wheelchair is an indoor / outdoor powered wheelchair that is battery operated. The product has a metal frame with four wheels and front anti tipping devices, adjustable seat with armrests, and a controller attached to one armrest. The controller allows the rider to control the movement of the chair. The chair can be disassembled for transport and is provided with a battery charger.

Intended Use of Device:
The Tuffcare Cruiser PP5500 Challenger powered wheelchair provides enhanced mobility to physically challenged persons limited to a sitting position.

Technological Characteristics:
The device features and use parameters of the Cruiser PP5500 Challenger powered wheelchair and the Pronto M51 powered wheelchair are very similar. Both have tubular metal frames, are batteries operated, have two motors, and have automatic braking systems. Both use similar controller. Battery chargers and instructions for their use are supplied with both chairs. Use parameters are very similar as well, with minor variations in such areas as travel range and maximum speed.

Testing Conducted:
Test listed in the Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles, July 1995, were conducted and the results included in the subject 510(k) submission.

Performance Testing:
Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2008

E1 Enterprises Incorporated
% Mr. Jack Cheng
Operation Manager
1290 Southwest 30th Avenue
Pompano Beach, Florida 33069

Re: K080385
Trade/Device Name: Cruiser PP5500 Challenger Powered Wheelchair.
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: 89ITI
Dated: April 14, 2008
Received: May 05, 2008

Dear Mr. Cheng:

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.

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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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the 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

Cruiser PP5500 Challenger Powered Wheelchair
510(K) Notification

INDICATIONS FOR USE

510(k) Number (if known) K080385

Device Name: Cruiser PP5500 Challenger Powered Wheelchair.

Indications for Use:

To provide enhanced mobility to physically challenged persons limited to a sitting position.

Prescription Use _____ AND / OR Over - The - Counter Use X

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. O'Neil for man
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K080385