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THE TITANIUM WHEELCHAIR COMPANY

510(k) SUMMARY

Date: February 26, 2002

Present by:

Ms. Sandra Gladstone
TiSport
1426 East Third Avenue
Kennewick, WA 99337
509-586-6117 ext. 260
509-586-2413 fax

Trade / Proprietary Name: TiPower TR RimPower & TiPower TRA RimPower

Common Name: Power/manual wheelchair

Classification Name: Powered Wheelchair (per 21 CFR section 890.3850)

Classification: Class II

Panel: Physical Medicine Device Prosthetic Devices Subpart D

Product Code: 890.3860 (Powered Wheelchair)

Legally Marketed Device Claiming Equivalence To: Commuter (K934232)

Description of Device: The TiPower TR Rim Power and TiPower TRA RimPower are rigid power/manual titanium wheelchairs.

Intended Use of the Device: The intended use of this device is the same as the predicate device, the Commuter, manufactured by Fortress Lite-Style Wheelchairs, Inc. It is intended to provide mobility to physically impaired individuals while providing them with a power or manual propulsion method.

Target Population: The specific medical conditions for which the device is indicated are listed as, but not limited to:

Spinal chord injury
Stoke/CVA
Post Polio Syndrome
Spina Bifada
Amputee
Multiple Sclerosis
Arthrogriposis
Muscular Dystrophy
Lower and upper extremity paralysis

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Testing Results: Meets the requirements of the ISO 7176 Parts 1, 3, 5, 7,and 8 Standards (other parts not applicable) and ANSI/RESNA WC/Vol. 2-1998 Section 21 and EN 12184;1999.

Device Comparison: The differences between the submitted device and the predicate device is that TiPower TR Rim Power and TiPower TRA RimPower chairs are both rigid chairs where the Commuter is a folding chair. Also the materials used in the manufacturing of the frames are different. Our chair is made with titanium the Commuter is made with aluminum. TiSport believes that manufacturing the frames out of titanium vs. aluminum is a benefit not only from a safety perspective but clinically as well because of titanium's proven superior strength-to-weight ratio and its natural ability to absorb vibration. The power pack is made from a different company than the Commuter power pack. The power unit on the TiPower chair performs the same function as the Commuter's power unit but we believe it is a better power unit because the battery is significantly smaller and lighter and is more energy efficient. The motor is in the hub of the wheel and the chair requires less human propulsion to move the chair. The other difference is the TiPower models offer a wider range of customization for the end user allowing for a better opportunity to properly "fit" the end user in a clinical setting as well as ensuring better safety and access to the chairs options and accessories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2002

Ms. Sandra Gladstone
Vice President Operations
TiSport
1426 East Third Avenue
Kennewick, WA 99337

Re: K020639
Trade Name: TiPower TR RimPower and TiPower TRA RimPower
Regulatory Number: 890.3860
Regulatory Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: April 12, 2002
Received: April 15, 2002

Dear Ms. Gladstone:

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" (21CFR 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 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): K020639

DEVICE NAME: TiPower TR RimPower & TiPower TRA RimPower

INDICATIONS FOR USE:

Indication for Use:

The intended use of this device (power/manual wheelchair) is the same as the predicate device, the Commuter (K934232). The intended use for the power/manual wheelchair is to provide mobility to physically impaired individuals. These chairs will allow the user to have a battery powered wheelchair or they can disengage the drive mechanism and have a manual wheelchair.

The specific medical conditions for which the device is indicated are listed as, but not limited to:

Spinal chord injury
Stoke/CVA
Post Polio Syndrome
Spina Bifada
Amputee
Multiple Sclerosis
Arthrogriposis
Muscular Dystrophy
Lower and upper extremity paralysis

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR 801.109) OR Over-The-Counter-Use_____ (Optional Format 1-2-96)

for Mark N Millar

(Division Sign-Off)
Division of [illegible]
and Neurological Devices

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510(k) Number K020639