2/26/99

THE TITANIUM SPORTSCHAIR COMPANY

K990358

510(k) SUMMARY

Date: February 4, 1999

Present by:

Ms. Sandra Gladstone
TiSport
1426 East Third Avenue
Kennewick, WA 99337
509-586-6117 ext. 233
509-586-2413 fax

Trade / Proprietary Name: Cross Sport

Common Name: Rigid Wheelchair

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

Classification: Class I

Panel: Physical Medicine

Product Code: 89IOR (Mechanical Wheelchair)

Legally Marketed Device Claiming Equivalence To: Shadow Rigid (K925451)

Description of Device: The Cross-Sport manual titanium wheelchair is a custom, rigid, everyday/sport chair manufactured to the specifications of the intended user.

Intended Use of the Device: The intended use of this device (manual wheelchair) is to provide mobility to physically impaired individuals. The manual wheelchair is intended for on-going "everyday" use and/or recreational sports applications.

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

Spinal chord injury
Post polio
Spina Bifada
Amputee

Testing Results: Meets the requirements of the ISO Standards.

Device Comparison: There are no significant differences between the submitted device and the predicate device (k925451). The only apparent differences between the Shadow rigid wheelchair and the TiSport Cross-Sport are the materials used in the manufacture of the frame and the degree of customization offered to the consumer/operator. TiSport believes that manufacturing the frame of the Cross-Sport out of titanium vs. chromoly is a benefit not only from a safety perspective but clinically as well because of titanium's proven superior strength-to-weight ratio. The degree of customization allows for a better opportunity to properly "fit" the operator 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

FEB 26 1999

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

Re: K990358
Trade Name: Cross-Sport, Rigid Wheelchair
Regulatory Class: I
Product Code: IOR
Dated: February 4, 1999
Received: February 5, 1999

Dear Ms. Gladstone:

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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

501(k) Number (if known): K990358

Devise Name: Cross Sport

Indication for Use:

The intended use of this device (manual wheelchair) is the same as the predicate device (Shadow rigid wheelchair {K925451} by Magic In Motion now owned by Quickie).

It is intended to provide mobility to physically impaired individuals. The manual wheelchair is intended for on-going "everyday" use and/or recreational sports applications.

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

Spinal chord injury
Post polio
Spina Bifada
Amputee

(PLEASE DO NOT WIRTE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990358

Prescription Use _____ OR Over-the-Counter Use X
(Per 21 CFR 801.109)