K023606

NOV 1 9 2002

1 OF 3

THE ULTIMATE RIDE

9. 501(k) SUMMARY

9.1. Date:

October 25, 2002

9.2. Submitted By:

TiSport, LLC
1426 East Third Avenue
Kennewick, WA 99337
Phone: 509-586-6117
Fax: 509-586-2413

9.3. Contact Person:

Richard S. Forman
Vice President – Legal and Business Affairs
TiSport, LLC
1426 East Third Avenue
Kennewick, WA 99337
Phone: 509-586-6117, Ext. 238
Fax: 509-586-2413

9.4. Trade/Proprietary Name of Device:

TiLite YG and TiLite YGS

9.5. Common Name of Device:

Growable, Manual, Rigid Wheelchair

9.6. Classification Name of Device:

Wheelchair, Mechanical (per 21 CFR section 890.3850)

9.7. Classification of Device:

Class I

9.8. Panel:

Physical Medicine - Prosthetic Devices Subpart D – 890

9.9. Product Code:

89IOR

9.10. Legally Marketed Predicate Device For Claimed Equivalence:

Zippie® Rigid Manual Wheelchair (K890050)

9.11. Description of Device:

The TiLite YG and YGS model wheelchairs are rigid manual titanium wheelchairs.

9.12. Intended Use of the Device:

The intended use of this device (growable, manual, rigid wheelchair) is the same as the predicate device. The intended use for the manual wheelchair is to provide mobility to physically impaired children. The manual wheelchair is intended for ongoing daily use and is designed so that the wheelchair can be adjusted as the user grows.

9.13. Target Population:

This device is indicated for individuals with the specific medical conditions listed, but the indications are not necessarily limited to such conditions:

- Amputee;
- Arthritis;
- Arthrogriposis;
- Cerebral Palsy;
- geriatric conditions;
- head injury or trauma;
- hemiplegic;
- Multiple Sclerosis;
- Muscular Dystrophy;
- paraplegic;
- Polio;
- quadraplegic;
- Spina Bifida;
- Stoke/CVA;
- tetraplegic; and
- other immobilizing or debilitating conditions, including spinal cord injuries and other lower and upper extremity paralysis

9.14. Testing Results:

Meets the requirements of the ISO 7176 Parts 1, 3, 5, 7,and 8.

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THE ULTIMATE RIDE

9.15. Device Comparison:

The principal differences between the submitted device and the predicate device are that TiLite YG and YGS series wheel chairs are the materials used in the manufacturing of the frames. The TiLite YG and YGS wheelchairs are made with titanium whereas the predicate device is made with aluminum. TiSport believes that titanium frames provide certain benefits when compared with aluminum frames from a safety perspective and a clinical perspective because of titanium's proven superior strength-to-weight ratio and its natural ability to absorb vibration. Accordingly, for example, the TiLite YG and YGS wheelchairs can accommodate at 250-lb. Passenger, whereas the predicate device can accommodate only a 150-lb. passenger.

The other difference is that the TiLite YG and YGS models offer a wider range of customization for the end user. TiSport believes that greater customization options allows 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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2002

TiSport, LLC
Richard S. Forman
Vice President
1426 East Third Avenue
Kennewick, Washington 99337-9669

Re: K023606
Trade/Device Name: Tilite YG and Tilite YGS
Regulation Number: 890.3850
Regulation Name: Wheelchair, mechanical
Regulatory Class: Class I
Product Code: IOR
Dated: October 25, 2002
Received: October 28, 2002

Dear Mr. Forman:

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

K023606

7. STATEMENT OF INDICATIONS FOR USE

7.1. Device Name:

TiLite YG and TiLite YGR

7.2. Indication for Use:

The intended use of this device (growable, manual, rigid wheelchair) is the same as the predicate device, the Zippie® (growable, manual, rigid wheelchair) manufactured by Sunrise Medical Inc. The intended use for the growable, manual, rigid wheelchair is to provide mobility to physically impaired children. The manual wheelchair is intended for ongoing daily use and is designed so that the wheelchair can be adjusted as the user grows.

This device is indicated for individuals with the specific medical conditions listed, but the indications are not necessarily limited to such conditions:

- Amputee;
- Arthritis;
- Arthrogriposis;
- Cerebral Palsy;
- geriatric conditions;
- head injury or trauma;
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- paraplegic;
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- quadraplegic;
- Spina Bifida;
- Stoke/CVA;
- tetraplegic; and
- other immobilizing or debilitating conditions, including spinal cord injuries and other lower and upper extremity paralysis

for Mark N Melkerson

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510(k) Number K023606