K072311

SEP 21 2007

510(k) SUMMARY

(As Required by 21 CFR 807.92(c))

Submitted By:

TiSport, LLC
1426 East Third Avenue
Kennewick, WA 99337
Telephone: 509-586-6117
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Contact Person:

Richard S. Forman, President & Chief Legal Officer

Date:

August 15, 2007

Trade Name of Device:

TiLite Aero X

Common Name of Device:

Folding Manual Wheelchair

Classification Name of Device:

Wheelchair, Mechanical (21 CFR 890.3850; Product Code IOR)

Classification of Device:

Class I

Panel:

Physical Medicine Prosthetic Devices

Legally Marketed Predicate for Claimed Substantial Equivalence:

Quickie 2HP (K890050) manufactured by Sunrise Medical, Inc., successor to Mobility Designs, Inc.

Description of Device:

The TiLite Aero X is a folding manual wheelchair. The frame components of the TiLite Aero X are tubular aluminum alloy. The folding mechanism components of the TiLite Aero X are extruded aluminum alloy.

Intended Use of Device:

The intended use for the TiLite Aero X is to provide mobility to physically impaired individuals. The TiLite Aero X folding manual wheelchair is intended for ongoing daily use.

Target Patient Population:

The TiLite Aero X device is indicated for individuals with the specific medical conditions listed, but the indications are not necessarily limited to such specific medical conditions: Amputee; Arthritis; Arthrogriposis; Cerebral Palsy; Geriatric Conditions; Head Injury or Trauma; Hemiplegic; Multiple Sclerosis; Muscular Dystrophy; Paraplegic; Polio; Quadraplegic; Spina Bifida; Stroke/CVA; Tetraplegic; and other immobilizing or debilitating conditions, including spinal cord injuries and other lower and upper extremity paralysis

Device Comparison:

There are no significant differences between the TiLite Aero X and the predicate device. The only apparent difference between the predicate device and the TiLite Aero X is that the TiLite Aero X offers the ability to customize and adjust the device to a greater degree than does the predicate device. The degree of customization and adjustment allows for a better opportunity to properly "fit" the user/operator of the wheelchair in a clinical setting and should permit better safety and access to the product's options and accessories. There are also certain technological differences between the TiLite Aero X and the predicate device that result in improved functionality. For example, the mechanism to add camber to the rear wheels uses camber plugs on the TiLite Aero X whereas the mechanism to add camber to the rear wheels uses washers on the predicate device. The mechanism to attach the front casters to the TiLite Aero X allows for a much greater degree of adjustability forward and rearward, whereas there are only two positions in which the front casters can be mounted on the predicate device.

Testing Results:

The TiLite Aero X will meet the requirements of ANSI/RESNA WC/Volume 1: 1998, Sections 1, 5, 7, 8, 16 and 93.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2007

TiSport, LLC
% Mr. Richard S. Forman
President & Chief Legal Officer
1426 East Third Avenue
Kenwick, WA 99337

Re: K072311
Trade/Device Name: TiLite Aero X
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: August 15, 2007
Received: August 17, 2007

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), 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 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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name:

TiLite Aero X

Indications for Use:

The intended use for the TiLite Aero X is to provide mobility to physically impaired individuals.

Prescription Use **Yes** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use **Yes** (21 CFR 801 Subpart C)

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

(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number k072311