DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 2, 2017

Tzora Active Systems Ltd.
% Moshe Rosenberg
Regulatory Consultant
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as St. (pob 124)
Kfar Saba, 4442520 IL

Re: K160835
Trade/Device Name: Titan 3W
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: December 27, 2016
Received: January 3, 2017

Dear Mr. Rosenberg:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Hoffmann -S
2017.02.02 10:58:44 -05'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160835

Device Name
Titan 3W

Indications for Use *(Describe)*
The Titan 3W is a mobility assistive device for indoor and outdoor use on mild terrain. It is not used as a transportation vehicle on roads and freeways used by cars.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SUMMARY OF SAFETY AND EFFECTIVENESS

K160835
(Premarket Notification [510(k)] Number)

1. Submitter Information

Manufacturer Name and Address
Tzora Active Systems Ltd.
Kibbutz Tzora,
9980300,
Israel

Official Correspondent
Moshe Rosenberg / Ahava Stein
A. Stein – Regulatory Affairs Consulting Ltd.
20 Hata'as St. (Beit Hapaamon, Suite 102)
Kfar Saba 4442520,
Israel

2. Date Prepared: February 2, 2017

3. Device Name Titan

Proprietary Name: Titan 3W

Common Name: Vehicle, Motorized 3-Wheeled

FDA Classification Name: 21 CFR 890.3800; Vehicle, Motorized 3-Wheeled

FDA Classification: Class II, Product Code INI

4. Predicate Devices

The Titan 3W is substantially equivalent to the following devices:

Manufacturer	Device	510(k)	Date Cleared
Tzora Active Systems Ltd.	Titan 4W	K150086	August 5, 2015

5. Device Description

The Titan 3W scooter is an electrically powered scooter. It is intended to be used by individuals that are able to walk, but suffer from mobility limitations. The user must have sufficient arm and leg strength to get on and off the Titan 3W alone and to safely steer under all driving conditions.

The Titan 3W is intended for indoor use and outdoor use. The Titan 3W has reflectors and lights, which should be used in the dark or in limited visibility conditions.

The Titan 3W can be folded and disassembled into two parts, the Front Frame and the Rear Frame. Separating both frame parts allows for easy storage and enables portability of the Titan 3W.
The Front Frame consists of the steering column, control panel, front wheels, footrest plate and seat.
The Rear Frame consists of the motor, controller and battery holders.

The control panel houses all the controls for operating the device. The control panel has a key switch for turning the device on and off, a lever for forward/reverse driving, knobs and switches for speed adjustment and lights (front and rear lights, indicators and hazard lights). The control panel also contains the control indicator for the status of the device and a battery gauge.
The LED control indicator shows the status of the scooter: steady light mean that all is well, blinking indicates an issue. The number of flashes indicate the type of issue. The User Manual contains a troubleshooting section where each type of error and its solution is specified.

The steering column can be adjusted and put it in the position which is most comfortable for the operator.

6. Indications for Use

The Titan 3W is a mobility assistive device for indoor and outdoor use on mild terrain. It is not used as a transportation vehicle on roads and freeways used by cars.

This Indication for Use statement is identical to that of the previously cleared Titan 4W.

7. Performance Testing

The following performance and safety tests were conducted with the Titan 3W:

- ISO 7176-1:2014 Wheelchairs – Part 1: Determination of static stability
- ISO 7176-2:2001 Wheelchairs – Part 2: Determination of dynamic stability of electric wheelchairs
- ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass and manoeuvring space
- ISO 7176-6:2001 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
- ISO 7176-7:1998 Wheelchairs – Part 7: Measurement of seating and wheel dimensions
- ISO 7176-8:2014 Wheelchairs – Part 8: Requirements and test methods for static, impact and fatigue strengths
- ISO 7176-10:2008 Wheelchairs – Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
- ISO 7176-15:1996 Wheelchairs – Part 15: Requirements for information disclosure, documentation and labeling
- ISO 7176-21:2009 Wheelchairs – Part Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- ISO 7176-25:2013 Wheelchairs – Part 25: Batteries and chargers for powered wheelchairs

The following performance and safety tests were conducted with the Titan 4W and the results are also valid for the Titan 3W, since the modification does not affect the requirements of these standards:

- ISO 7176-3:2012 Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-4:2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
- ISO 7176-9:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs

- ISO 7176-13:1989 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
- ISO 7176-14:2008 Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
- ISO 7176-16:2012 Wheelchairs - Part 16: Resistance to ignition of postural support devices

Regarding the biocompatibility, there are three parts that can come into touch with intact skin: the seat, the handgrips and the armrests.
The seat materials, handgrips and armrests are identical to those used for the previously cleared Titan 4W.
No new materials have been introduced in the Titan and therefore biocompatibility retesting is not required.

8. Technological Characteristics Compared to Predicate Device

Control Panel

The Titan 3W has the same control panel as the predicate device.

Maximum speed

The Titan 3W can reach a maximum speed of 6.8 mph, whereas the predicate device has a maximum speed of 7.3 mph. This is due to the difference in size of the rear wheels. The minimum braking distance remained the same: 2.2 m.

Batteries

The Titan 3W batteries are identical to the batteries of the predicate device: two 12V 26A/h sealed lead acid batteries.

Seat

The Titan 3W has the same seat and armrests as the predicate device.

Frame

The Titan 3W has the same foldable and detachable frame as the predicate device. The rear frame of the Titan 3W is identical to the predicate device. The front frame of the Titan 3W is slightly different due to the difference in front wheels.

Wheels

The Titan 3W has 3 wheels (1 front, 2 rear wheels), whereas the predicate device has 4 wheels (2 front, 2 rear wheels).

Motor

The Titan 3W is propelled by the same transaxle motor with electromagnetic brake as the predicate device. This motor unit is attached to the rear of the frame and has the rear wheels attached to it, identical to the predicate device.

The differences in the above specifications do not adversely affect the safety and effectiveness and performance of the Titan 3W. The Titan 3W was tested according to the in section 7 aforementioned standards and found compliant.

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the indications for use of the Titan 3W are substantially equivalent to the predicate device cited above.

Technical Data

Item	Titan 3W	Titan 4W
Maximum speed	11.0 km/h (6.8 mph)	11.8 km/h (7.3 mph)
Minimum braking distance and time	<2.2 m (7.2 ft), <1 s	
Power supply	24V from 2 12V-26Ah batteries.	
Estimated range	25 km (15.5 miles) depending on operating conditions	
Climbing slope	8° (14%)	
Curb (step) climbing	50 mm. (2 in.) maximum (see note on page 9)	
Ground clearance	8 cm. (3.1 in.)	
Maximum load	136 kg. (300 lbs.)	
Liquid ingress protection	IPX4	
Scooter weight (excluding batteries)	45 kg (99.2 lbs.)	53 kg (116.8 lbs.)
Front chassis weight (Including seat)	22 kg (48.5 lbs.)	27 kg (59.5 lbs.)
Rear chassis weight (excluding batteries)	23 kg (50.7 lbs.)	26 kg (57.3 lbs.)

Item	Titan 3W	Titan 4W
Rear chassis weight (including batteries)	42 kg (92.6 lbs.)	45 kg (99.2 lbs.)
Battery pack weight	9.5 kg (20.9 lbs.) x 2	
Dimensions (Length, Width, Height)	139X60X95 cm (54.7x23.6x37.4 in.)	137x62x95 cm (53.9x24.4x37.4 in.)

9. Conclusion

The performance testing and comparison to the predicate device demonstrate that the Titan 3W is as safe, as effective and performs as well as the legally marketed Titan 4W predicate device. Therefore, the Titan 3W is substantially equivalent to the Titan 4W.