DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 5, 2015

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

Re: K150086
Trade/Device Name: Titan 4W
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: April 26, 2015
Received: July 6, 2015

Dear Moshe 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); 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), 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,

Carlos L. Pena -S

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)*
K150086

Device Name
Titan 4W

Indications for Use *(Describe)*
The Titan 4W 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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510(k) SUMMARY

K150086
(Premarket Notification [510(k)] Number)

1. Submitter Information

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

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

2. Date Prepared: August 5, 2015

3. Device Name Titan 4W

Proprietary Name: Titan 4W

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 4W is substantially equivalent to the following device:

Manufacturer	Device	510(k)	Date Cleared
Tzora Active Systems Ltd.	Elite	K052204	February 15, 2006

5. Device Description

The Titan 4W 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 4W alone and to safely steer under all driving conditions.

The Titan 4W is intended for indoor use and outdoor use. The Titan 4W has reflectors and lights, which should be used in the dark or in limited visibility conditions.

The Titan 4W can be folded and disassembled into two parts. This allows for easy storage and enables portability of the Titan 4W.

6. Indications for Use

The Titan 4W 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.

7. Performance Standards

There are no performance standards under the Federal Food, Drug and Cosmetic Act, for the Titan 4W.

8. Performance Testing

The following performance, safety and usability tests were conducted with the Titan 4W:

- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (2007)
- ISO 7176 Wheelchairs -- Parts 1, 2, 3, 4, 5, 6, 8, 9, 10, 11, 13, 14, 15, 16, and 21.
- Usability Study validated the system’s usability by the intended user.

9. Technological Characteristics Compared to Predicate Device

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 4W are substantially equivalent to the predicate device cited above.