May 2, 2018

Tzora Active Systems Ltd.
% Moshe Rosenberg
Regulatory Consultant
A. Stein Regulatory Affairs Consulting Ltd.
20 Hataas St., Suite 102
Kfar Saba, 4442520 Il

Re: K172409
Trade/Device Name: Lite
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: March 28, 2018
Received: April 2, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172409

Device Name
Lite

Indications for Use *(Describe)*
The Lite is a mobility assistive device for indoor and outdoor use on pavements or 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SUMMARY OF SAFETY AND EFFECTIVENESS

K172409
(Premarket Notification [510(k)] Number)

1. Submitter Information

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

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

2. Date Prepared: May 2, 2018

3. Device Name Lite

Proprietary Name:	Lite
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 Lite is substantially equivalent to the following devices:

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

5. Device Description

The Lite 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 Lite alone and to safely steer under all driving conditions.

The Lite is intended for indoor use and restricted outdoor use on pavements or paved footpaths only.

The Lite can be folded. This allows for easy storage and enables portability of the Lite.

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 and a knob for speed adjustment. 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.

The armrests can be lifted to enable easy entry and exit from the scooter.

6. Indications for Use

The Lite 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.

These indications for use and intended use are identical to those of the predicate device.

7. Performance Testing

Testing was performed with the Lite to be in conformance with the following standards:

- 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 7176-3:2012 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 7176-5:2008 Wheelchairs – Part 5: Determination of overall 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 7176-9:2009 Wheelchairs – Part 9: Climatic tests for electric wheelchairs
- ISO 7176-10:2008 Wheelchairs – Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
- ISO 7176-11:2012 Wheelchairs – Test dummies
- 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 7176-15:1996 Wheelchairs – Part 15: Requirements for information disclosure, documentation and labeling
- ISO 7176-16:2012 Wheelchairs – Part 16: Resistance to ignition of postural support devices
- 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

8. Technological Characteristics Compared to Predicate Device

The following table shows a comparison between the Lite and the predicate Elite.

COMPARISON TABLE

Technological Characteristic	**Lite** **Tzora Active Systems Ltd.** **(K172409)**	**Elite** **Tzora Active Systems Ltd.** **(K052204)**
Product Code, Class	INI, Class II	INI, Class II
Indications for Use	The Lite is a mobility assistive device for indoor use and outdoor use on mild terrain. It is not used as a transportation vehicle on roads and freeways used by cars.	The Elite is a mobility assistive device for indoor use and outdoor use on mild terrain. It is not used as a transportation vehicle on roads and freeways used by cars.
Target Population	Individuals that are able to walk but suffer from minor mobility limitations.	Individuals that are able to walk but suffer from minor mobility limitations.
Environment Used	Indoor and outdoor	Indoor and outdoor
Energy Used / Delivered	No energy delivered	No energy delivered
Design:	The Lite consists of a foldable frame, foldable steering column and removable battery pack.	The Elite consists of a foldable frame, foldable and detachable steering column and removable battery pack.
- Mechanism of Action	Transaxle motor drive unit, propelling both rear wheels.	Pancake hub motor forming the front wheel.
- Components	- 2 Front Wheels – Flat Free PU 8x2” - 2 Rear Wheels – Flat Free PU 8x2” - Transaxle Motor - Controller - Frame - 2x 12V 12A/h Sealed Lead Acid Batteries - 2x 12V 12 A/h Lithium Batteries (optional)	- 1 Front Wheel - Flat Free PU 10x2” - 2 Rear Wheels – Flat Free PU 8x2” - Pancake hub motor - Controller - Front Frame - Rear Frame - 2x 12V 12A/h 2x 12V 7A/h (*discontinued)

Technological Characteristic	**Lite** **Tzora Active Systems Ltd.** **(K172409)**	**Elite** **Tzora Active Systems Ltd.** **(K052204)**
- Features	Maximum Speed 3.7 mph Turning Radius: 35” Carrying Capacity: 250 lbs Climbing Slope: 6° Curb Clearance: 1.6”	Maximum Speed: 3.7 mph Turning Radius: 37” Carrying Capacity: 250 lbs Climbing Slope: 6° Curb Clearance: 2”
- Dimensions	39x22x35”	43x22x35”
- Weight	Total: 66 lbs (Lead Acid), 58 lbs (Lithium) Frame: 48 lbs Battery Pack: 18 lbs (12A/h Lead Acid) 10 lbs (12A/h Lithium)	Total: 64 lbs Front Column: 24 lbs Rear Frame: 27 lbs Battery Pack: 18 lbs (12A/h Lead Acid)
Performance	Range: up to 8 mi (Lead Acid) up to 9.8 mi (Lithium)	Range: up to 8 mi (Lead Acid)
Human Factors	Control Panel consists of: - On/Off Key Switch - Control Lever Forward/Reverse - Speed Adjustment Knob - Battery Gauge - Status Indicator LED	Control Panel consists of: - On/Off Key Switch - Control Lever Forward/Reverse - Speed Adjustment Knob - Battery Gauge - Status Indicator LED
Standards Met	ISO 7176 series safety standards	ISO 7176 series safety
Materials	Frame: Stainless Steel Seat: Polypropylene Upholstery: Vinyl Covered Foam Armrests: Foam	Frame: Stainless Steel Seat: Polypropylene Upholstery: Vinyl Covered Foam Armrests: Foam
Biocompatibility	Materials are biocompatible	Materials are biocompatible

Technological Characteristic	Lite Tzora Active Systems Ltd. (K172409)	Elite Tzora Active Systems Ltd. (K052204)
Compatibility With the Environment and Other Devices	The Lite is compliant with the ISO 7176-21 standard.	The Elite is compliant with the IEC 60601-1-2 (EMC Compatibility) standard.
Electrical Safety	Power Requirements: 110-120 VAC / 60 Hz 220-240 VAC / 50 Hz The Lite is compliant with the ISO 7176 series safety standards.	Power Requirements: 110-120 VAC / 60 Hz 220-240 VAC / 50 Hz The Elite is compliant with the EN 12184 (Electrical Safety) standard.
Mechanical Safety	The Lite is compliant with the ISO 7176 series safety standards.	The Elite is compliant with the EN 12184 (Electrical Safety) standard.
Chemical Safety	Not Applicable	Not Applicable
Thermal Safety	The Lite is compliant with the ISO 7176 series safety standards.	The Elite is compliant with the EN 12184 (Electrical Safety) standard.
Radiation Safety	The Lite is compliant with the ISO 7176-21 standard.	The Elite is compliant with the IEC 60601-1-2 (EMC Compatibility) standard.

Control Panel

The Lite has the same control panel as the predicate device.

Maximum speed

The Lite can reach the same maximum speed of 3.7 mph as the predicate device (K052204). Also the minimum braking distance remained the same: 0.7 m.

Batteries

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

The Lite can also be provided with two 12V 12A/h lithium batteries.

Seat

The Lite has the same seat and armrests as the predicate device.

Frame

The Lite has a foldable frame, where the seat and the steering column can be folded down. The Elite has a foldable and detachable frame, where the steering column can be folded with the frame or it can be detached from the frame.

Wheels

The Lite has 4 wheels (2 front, 2 rear wheels), whereas the predicate device has 3 wheels (1 front, 2 rear wheels). The 4-wheel design is identical to the previously cleared EasyTravel (K012592).

Motor

The Lite is propelled by a transaxle motor with electromagnetic brake. This motor unit is attached to the rear of the frame and has the rear wheels attached to it. The predicate device is propelled by a pancake motor placed, with the electromagnetic brake, in the front drive wheel.

The differences in the above specifications do not adversely affect the safety and effectiveness and performance of the Lite. The Lite was tested to be in conformance with the in section 8 aforementioned standards and found compliant.

Standard	Subject: Lite (K172409)	Predicate: Elite (K052204)	Equivalent?
ISO 7176-1	Passed	Passed	Yes
ISO 7176-2	Passed	Passed	Yes
ISO 7176-3	Passed	Passed	Yes
ISO 7176-4	Passed	Passed	Yes
ISO 7176-5	Passed	Passed	Yes
ISO 7176-6	Passed	Passed	Yes
ISO 7176-7	Passed	Passed	Yes
ISO 7176-8	Passed	Passed	Yes
ISO 7176-9	Passed	Passed	Yes
ISO 7176-10	Passed	Passed	Yes
ISO 7176-11	Passed	Passed	Yes
ISO 7176-13	Passed	Passed	Yes
ISO 7176-14	Passed	Passed	Yes
ISO 7176-16	Passed	Passed	Yes
ISO 7176-21	Passed	Passed	Yes
ISO 7176-25	Passed	N/A	N/A

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

9. Conclusion

The performance testing and comparison to the predicate device demonstrate that the Lite is as safe, as effective and performs as well as the legally marketed Elite predicate device. Therefore, the Lite is substantially equivalent to the Elite and may be legally marketed in the USA.