510k Summary

The *Elite* Scooter is a mobility assistive device for indoor use and outdoor use on mild terrain. Not used as a transportation vehicle on roads and freeways used by cars. The *Elite* Scooter is an ultra-light, compact, portable vehicle.

It is designed for the use of active individuals that are able to walk short distances, but suffer from minor mobility limitations. The user must have sufficient arms and legs strength to be able to get on and off the Elite on his/her own and to steer without effort under all driving conditions. The maximum allowed weight of the user is 250 lbs.

The *Elite* features the patented Wheel Drive system that incorporates the motor in the front wheel for additional ease of steering

The innovation is restricted to the modification of the design and construction of the hub type magnet brush pancake motor and drive unit.

The Elite has the following main components:

- The Foldable rear frame and the Steering column made from steel tubular welded parts with an oven baked powder coated paint finish.
- A single drive wheel and two free turning rear wheels. All three wheels are Polyurethane flat free. The front wheel size is10"x2", the rear wheel size is 8"x2".
- The seat is made from two Polypropylene injected molded vinyl covered foam. The backrest folds down and latches for transportation. The seat is adapted and fitted to the foldable rear-frame.
- The front wheel drive with a DC permanent magnet brush pancake motor. Because the reduction gear is a spur gear and not worm gear it is a very efficient system.
- The hub assembly, comprises the drive wheel, pancake shaped PM dc motor, reduction gearbox and an electro-magnetic brake. It has a slick structure, compact size, high output torque, high efficiency and low noise. It has no moving parts; is fixed to the front fork of the Elite.
- An electro-magnetic brake connected to its rear shaft. The brake is released electrically by the controller during motor operation, and applied after the motor decelerates and comes to a stop. A mechanical spring automatically applies the brake in case of an electrical failure.
- The control is a forward/reverse wigwag type that can be operated by both left and right hand. A speed adjustment knob limits the maximum speed. There is a Power On/Off key switch on the control panel, a battery gauge and a LED for low battery and fault condition indication. The brake release toggle is on the control cover.
- The Controller from Penny and Giles Drives Technologies Ltd. (UK), conforms to all applicable international standards.
- The 12V battery packs are available in two sizes: the Mini-size pack contains 7.2Ah capacity batteries and the Jumbo size pack – 12Ah capacity. There is a short-circuit protection fuse in the Battery Pack.
- The 100-240 VAC charger charges the batteries either directly (off board) or via a socket on the front column with an inhibit feature that does not allow the scooter to be driven when the batteries are being charged.
- Carrying Basket placed below the seat

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2006

Mr. Alex Gonorovsky
Manager, Regulatory Affairs
Tzora Active Systems Ltd.
Kibbutz Tzora, 99803
Israel

Re: K052204
Trade/Device Name: The Elite - ultra-light, compact portable scooter
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: December 14, 2005
Received: January 10, 2006

Dear Mr. Gonorovsky:

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 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
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K052204

Device Name: *The Elite* - ultra-light, compact portable scooter

Indication for Use:

Mobility assistive device for indoor use and outdoor use on mild terrain. Not used as a transportation vehicle on roads and freeways used by cars.

Prescription Use _____ AND/OR Over-The-Counter Use [X]
(Part 21 CFR 801 Subpart D (21 CF 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052204