



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

October 4, 2016

Moving Life Ltd.  
% Mr. Igor Naroditsky  
RA adviser  
Igor Naroditsky, Medical Device Certification LLC  
Emeq Hashalom 26/2  
Yoqneam Illit, 20692 Israel

Re: K160909  
Trade/Device Name: ATTO Mobility Scooter  
Regulation Number: 21 CFR 890.3800  
Regulation Name: Motorized Three-Wheeled Vehicle  
Regulatory Class: Class II  
Product Code: INI  
Dated: July 30, 2016  
Received: August 8, 2016

Dear Mr. Naroditsky:

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,

**Michael J. Hoffmann -A**

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

## Indications for Use

510(k) Number (if known)

K160909

Device Name

ATTO Mobility Scooter

Indications for Use (Describe)

ATTO Mobility Scooter is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.

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

**K160909**

### A. Contact Details

Applicant Name: Nino A. Ransenberg, Chairman  
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Contact Name: Igor Naroditsky, RA Adviser  
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### B. Device Name:

Trade Name: ATTO Mobility Scooter

Model: Type I

Common Name: Vehicle, Motorized 3-Wheeled

Classification Name: Motorized three-wheeled vehicle; INI; 890.3800

### C. Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Manufacturer
K110165	INI	Luggie	Freerider Corporation

### D. Device Description

ATTO Mobility Scooter is an electrical battery powered, three-wheeled scooter intended to provide mobility for elderly or disabled individuals in a variety of indoor and outdoor settings. The ATTO is a collapsible electric scooter which has a front-wheel brushless DC hub motor. The scooter can be collapsed in 12 seconds, and can also be disassembled with ease.

The scooter controlled through a thumb throttle and protected by an electronic-release brake system, has a driving range of 15 km between charges. It is capable of carrying a driver

weighing up to 100 kg. It moves in both directions, and can handle a 6° slope. It can come to a full stop within 1.1m when on a horizontal plane and within 2.2 m when on a 6° slope.

**E. Intended Use/indications for use**

The Moving Life ATTO Mobility Scooter is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.

**F. Substantial Equivalence Comparison**

The Moving Life ATTO Mobility Scooter is as safe and effective as the Luggie (K110165). The Moving Life ATTO Mobility Scooter has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Moving Life ATTO Mobility Scooter and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Moving Life ATTO Mobility Scooter is as safe and effective as the Luggie (K110165). Thus, the ATTO Mobility Scooter is substantially equivalent.

<b>Model</b>	<b>ATTO Mobility Scooter</b>	<b>Luggie</b>
K number	K160909	K110165
Indication for Use	The Moving Life ATTO Mobility Scooter is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.	The device provides transportation for an elderly or disabled person. It can be used in variety of indoor and outdoor settings.
Front wheel size	203 x 27 mm	200 x 50 mm
Rear wheel size	228 x 57 mm	200 x 50 mm
Ground clearance	100 mm	64 mm / 2.5 inches
Number of wheels	3	3 (double front wheel)
Length	1200 mm	1000 mm
Width	560 mm	455 mm / 18 inches
Max load	100 kg	114 kg / 250 pounds
Required width of angled corridor	1000 mm	762 mm
Turn radius	135.0 cm	103.75 cm / 40.85 inches
Battery	Li-Ion battery 48V 5.2 ah	Li-Ion battery 24V 8.5 ah

Charger	AC input.100-240 volt, 50/60Hz, DC output 54.6 volt. 2 Amp for lithium-ion battery	AC input.100-240 volt, 50/60Hz, DC output 24 volt. 5 Amp for li-ion battery
Type of controller	Microprocessor based, proportional and integral controller which continually monitors the ATTO systems.	Microprocessor based which continually monitors the Luggie scooter's systems
Maximum speed (forward)	6.4 km/h	6 km/h
Maximum speed (reverse)	4 km/h	3.52 km/h
Travel distance	15 km	18 km
Electrical System:	48 volt DC	24 volt DC
Drive system	Front wheel, direct drive.	Rear wheel, direct drive via sealed drive axle
Motor	48 volt DC, Brushless electric motor with 3 phases & sensors	24 volt DC. Permanent magnet totally enclosed for outdoor use. Internal brushes. 3.0 Amp (no load)
Brake	Spring Applied Electrical Released Brakes with freewheel mode	Automatic dynamic regenerating braking system with spring activated magnetic solenoid parking brake and freewheel facility.
Tiller	Adjustable locking for driving comfort	Same
Speed Control	PID velocity and current control	Proportional state of the art design for safety and smooth operation incorporated with 'Fault' diagnosis.
Seat	Folding seat	Contoured adjustable seat with height adjustment. Armrest are optional with multiple width adjustments

### G. Non-clinical Testing

Moving Life ATTO Mobility Scooter is designed and tested in accordance with the ISO 7176 standard series, including all relevant sections i.e. Section 1, Section 2, Section 3, Section 4, Section 5, Section 6, Section 7, Section 8, Section 9, Section 10, Section 11, Section 13,

Section 14, Section 15, Section 16, and Section 21. The battery and charger conform to the IEC 62133 standard. All Performance tests met the predetermined acceptance values. The Moving Life ATTO Mobility Scooter functioned as intended and its functionality observed was as expected.

#### **H. Clinical Testing**

No clinical testing is included in this submission.

#### **I. Technological Characteristics**

An electrical battery powered, three-wheeled scooter intended to provide mobility for elderly or disabled individuals in a variety of indoor and outdoor settings is the technological principle for both the subject and predicate devices. It is based on the use of electrical motor powered by rechargeable battery through electrical controller mounted on same three wheel platform. Thus, based on the following similar technological elements:

- DC motor, is used to rotate the wheel forward or backward.
- Li Ion rechargeable battery, to power the system.
- The controller provides a movement and speed control.
- Three wheel based platform provides a stable and flexible platform for indoor and outdoor use.
- Brake system utilizes a same dynamic principles and technology.
- Both systems are operated via two handles tiller.

The following technological differences exist between the subject and predicate devices:

- The subject device reach maximum 15 kilometer of travel distance in comparing to 18 in the predicate.
- The subject device utilizes 48 V 5.2 ah Li-Ion battery in comparing to 24 V 8.5ah at the predicate.
- The subject device has only off board charger in comparing to the On and Off board charger attached to the predicate device.
- The subject device has 48 V electrical systems in comparison to the 24V in the predicate.
- The subject device use a front wheel driving system in comparing to rear wheel driving in the predicate.
- A speed control archived through PID velocity and current control in the subject device in compare to the proportional state of the art design for safety and smooth operation incorporated with 'Fault' diagnosis in the predicate.

At a high level, the subject and predicate devices are based on the following same technological elements: Both are electric scooters that are battery operated and have automatic braking systems. Batteries and battery chargers are provided with each scooter. Performance parameters of the devices are very similar. There are some minor technological differences between the proposed ATTO Mobility Scooter and the commercially available Luggie (K110165). None of these differences raise new issues of safety and effectiveness.

The additional and minor technology differences between the proposed ATTO Mobility Scooter Type I and its predicate, the Luggie (K110165) is folding mechanism of the proposed device and the fact that it can be disassembled into two parts. The proposed device has a mechanism that retracts the rear wheels while folding the seat. In addition, the proposed device has a separation mechanism that allows the disassembly of the vehicle into two main parts.

## **J. Conclusion**

The safety and effectiveness of the ATTO Mobility Scooter were demonstrated by the testing in compliance with national and international standards. The intended use, basic technology, and the features of the ATTO Mobility Scooter are similar to the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.