May 19, 2023

Moving Life Ltd
Igor Naroditsky
RA Adviser
Havat Alenby
Netzer Sereni, 7039500
Israel

Re: K222703
Trade/Device Name: ATTO Mobility Scooter (ATTO);ATTO Mobility Scooter (ATTO SPORT);ATTO Mobility Scooter (ATTO SPORT MAX)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: April 17, 2023
Received: April 17, 2023

Dear Igor 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222703

Device Name
ATTO Mobility Scooter (ATTO)
ATTO Mobility Scooter (ATTO SPORT)
ATTO Mobility Scooter (ATTO SPORT MAX)

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.

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."

510(k) SUMMARY (K222703)

ATTO Mobility Scooter

A. Contact Details

Applicant Name: Moving Life Ltd
Havat Allenby, Netzer Sereni, 7039500 Israel
Contact Name: Igor Naroditsky, Regulatory Adviser
Phone: + 972 54 4384386
Date Prepared: Aug 15, 2022

B. Device Name:

Trade Name: ATTO Mobility Scooter

Models: ATTO, ATTO SPORT, ATTO SPORT MAX

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
K160909	INI	ATTO Mobility Scooter	Moving Life Ltd

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 up to 20 km between charges. It is capable of carrying a driver weighing up to 136 (for ATTO MAX) kg. It moves both directions and handles 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.

The differences between the ATTO Mobility Scooter and its predicates are:

- Introduction of the two additional models, ATTO SPORT, and ATTO SPORT MAX with
- Additional Manual Front Wheal brake for extra safety

- Software Speed control feature (in ATTO SPORT, and ATTO SPORT MAX only)
- Enhanced LCD display
- Extra wide rear wheel
- Rear light handle
- Powerful LED Headlights
- Shock-absorbing airless NPT tires
- Regenerative braking control system
- Modified controller
- Modified charger and battery

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 proposed ATTO Mobility Scooter is as safe and effective as the ATTO Mobility Scooter (K160909) by Moving Life. The Scooter has the same intended uses and same 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 ATTO Mobility Scooter (K160909) by Moving Life. Thus, the proposed ATTO Mobility Scooter is substantially equivalent.

G. Substantial Equivalence Chart

Model	Predicate ATTO Mobility Scooter (K160909)	Proposed ATTO Mobility Scooter (K222703)
Indication for Use	The Moving Life ATTO Mobility Scooter is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.	The Moving Life ATTO Mobility Scooter is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.
Front wheel size	203 X 27 mm	8 in
Rear wheel size	228 X 57 mm	9 in
Ground clearance	100 mm	100 mm
Number of wheels	3	3
Length	1200 mm	1200 mm
Width	560 mm	560 mm
Max load	100 kg	120 kg for ATTO and ATTO Sport. 136 kg for ATTO SPORT MAX
Required width of angled corridor	1000 mm	1000 mm

Model	Predicate ATTO Mobility Scooter (K160909)	Proposed ATTO Mobility Scooter (K222703)
Turn radius	1350 mm	1350 mm
Battery	Li-Ion battery 48V 5.2 ah	Li-ion Battery 5.2 Ah; DC 48 V; 249.6 Wh
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 54.6 volt. 2 Amp for lithium-ion battery
Type of controller	Microprocessor based, proportional and integral controller which continually monitors the ATTO systems.	Microprocessor based, proportional and integral controller which continually monitors the ATTO systems.
Maximum speed (forward)	6.4 km/h	6.4 km/h for ATTO and ATTO Max. 9.6 km/h for Max SPORT
Maximum speed (reverse)	4 km/h	4 km/h
Travel distance	15 km	20/17 km
Electrical System:	48-volt DC	48-volt DC
Drive system	Front wheel, direct drive.	Front wheel, direct drive.
Motor	48-volt DC, Brushless electric motor	48-volt DC, Brushless electric motor
Brake	Spring Applied Electrical Released Brakes with freewheel mode	Spring Applied Electrical Released Brakes with freewheel mode with regenerative braking control system. Additional front disk brake for extra safety
Tiller	Adjustable locking for driving comfort	Adjustable locking for driving comfort
Braking Time	Not publicly available	.5s
Braking Distance	Not publicly available	1.1m
Speed Control	Velocity and current control	Velocity and current control
Seat	Folding seat	Folding seat

H. Non-clinical Testing

Moving Life ATTO Mobility Scooter is designed in accordance with the ISO7176 series including all relevant sections i.e., Section 1, Section 2, Section 3, Section 4, Section 5, Section 6, Section 9, Section 10, Section 11, Section 13, Section 14, Section 15, Section 16, Section 21 and Section 25, etc. ATTO performance and safety testing is conducted according to EN 12184:2014. All Performance testing met the predetermined acceptance values. The Moving Life ATTO Mobility Scooter functioned as intended and its functionality observed was as expected.

I. Clinical Testing

No clinical testing is included in this submission.

J. Technological Characteristics

ATTO Mobility Scooter is a same as the commercially available ATTO Mobility Scooter (K160909) by Moving Life and based on the same fundamental technology as the predicate devices. 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 technology differences between the proposed ATTO Mobility Scooter and the commercially available ATTO Mobility Scooter (K160909) by Moving Life. None of these differences raises new issues of safety and effectiveness.

K. 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. No new issues of safety and effectiveness is raised by the differences between the proposed ATTO Mobility Scooter and its predicate devices.