



November 29, 2017

Advanced Vehicle Concepts Ltd.
% Vaibhav A. Rajal
Official Correspondent for Advanced Vehicle Concepts Ltd.
mdi Consultants, Inc.
55 Northern Blvd. Suite 200
Great Neck, New York 11021

Re: K170634

Trade/Device Name: Quingo Classic Power Scooter S1301, Quingo Flyte Power Scooter S551, Quingo
Toura Power Scooter S350
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: October 24, 2017
Received: October 25, 2017

Dear Mr. Rajal:

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

Indications for Use

510(k) Number (if known)

K170634

Device Name

Advanced Vehicle Concepts Ltd. Quingo Classic Power Scooter, S1301, Quingo Flyte Power Scooter, S551, Quingo Toura Power Scooter, S350.

Indications for Use (Describe)

The devices provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.

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

The assigned 510(k) number is: K170634

1. Date Prepared: November 28, 2017

Submitter's Identification:

Contact Person: Mr. Mark Nicholls
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2. Device Trade/Proprietary Name:

Advanced Vehicle Concepts Ltd. Quingo Classic Power Scooter, S1301, Quingo Flyte Power Scooter, S551, Quingo Toura Power Scooter, S350.

Common Name: Motorized 3 Wheeled Vehicles (5 Wheeled Scooters)

Classification Name:

Regulation Number: 21 CFR Part 890.3800
Regulation Name: Motorized 3 Wheeled Vehicles (5 Wheeled Scooters)
Regulatory Class: II
Product Code: INI
Classification Panel: Physical Medicine

3. Predicate Device:

Merits Health Products Co., Ltd., Merits Transformer, Model S941, K142162

4. Device Description

There are three models in the Quingo range for this subject 510(k)

Quingo Flyte Power Scooter, S551 (transportable model), Quingo Classic Power Scooter, S1301 and Quingo Toura Power Scooter, S350 (pavement and higher speed models)

They all have very similar characteristics which are detailed below, with the main differences being: length, widths, motor size, controller size, and wheel size.

All the Quingo models scooter frames are a welded steel construction and they all include 2 rear wheels connected by a motor/ transaxle with an electromagnetic brake, batteries, and they all have 3 front wheels and a tiller to control its turning direction.

When the user activates the throttle lever, the controller receives a signal to release the brakes. With the brakes released, the scooters are allowed to move forwards or backward. When the user releases the throttle lever, the scooter slows to a stop and the brakes are automatically re-engaged. The electromechanical brakes allow the user to stop by letting go of the throttle lever. All the Quingo Models have an emergency parking brake, the lever for this brake is on the tiller and the brake itself is a carbon disc brake on to the front middle wheel.

This is best illustrated by the picture below:



The Quingo Classic Power Scooter, S1301 is battery powered, rear transaxle driven and is controlled by the Dynamics Rhino 2 DS70C amp controller. The user interface is a wig-wag control lever and a speed knob on the control panel. The S1301 is powered by two 12 VDC 35ah batteries. The batteries are charged by a 5A off-board charger connect with 3-pin microphone connector to charging socket on the tiller. The approximate driving range on fully charged batteries is up to 37 kilometers (23 miles). The scooter frame is a welded steel construction and includes 2 rear wheels connected by a motor/transaxle with an electromagnetic brake, batteries, 3 front wheels and a tiller to control its turning direction.

When the user activates the throttle lever, the controller receives a signal to release the brakes. With the brakes released, the scooter is allowed to move forward or backwards. When the user releases the throttle lever, the scooter slows to a stop and the brakes are automatically re-engaged. The electromechanical brakes allow the user to stop by letting go of the throttle lever.

The S1301 also has fitted to the tiller, an emergency/parking brake which works via a disc brake on to one of the front wheels.

The upholstery of the device complies with ISO 7176-16:2012, resistance to ignition of postural support devices.

The device can be operated on dry, level surfaces composed of concrete, blacktop, or asphalt under normal driving conditions.

The Quingo Toura Power Scooter, S350 is battery powered, rear transaxle driven and is controlled by the Dynamics Rhino 2 DS160 amp controller. The user interface is a wig-wag control lever and a speed knob on the control panel. The S350 is powered by two 12 VDC 100ah batteries. The batteries are charged by a 8A off-board charger connect with 3-pin microphone connector to charging socket on the tiller. The approximate driving range on fully charged batteries is up to 88 kilometers (55 miles). The scooter frame is a welded steel construction and includes 2 rear wheels connected by a motor/transaxle with an electromagnetic brake, batteries, 3 front wheels and a tiller to control its turning direction.

When the user activates the throttle lever, the controller receives a signal to release the brakes. With the brakes released, the scooter is allowed to move forward or backwards. When the user releases the throttle lever, the scooter slows to a stop and the brakes are automatically re-engaged. The electromechanical brakes allow the user to stop by letting go of the throttle lever.

The S350 also has fitted to the tiller, an emergency/parking brake which works via a disc brake on to one of the front wheels.

The upholstery of the device complies with ISO 7176-16:2012, resistance to ignition of postural support devices.

The device can be operated on dry, level surfaces composed of concrete, blacktop, or asphalt under normal driving conditions.

The Quingo Flyte Power Scooter, S551 is battery powered, rear transaxle driven and is controlled by the Dynamics Rhino 2 DS90C amp controller. The user interface is a wig-wag control lever and a speed knob on the control panel. The S551 is powered by four 12 VDC 22ah batteries. The batteries are charged by a 5A off-board charger connect with 3-pin microphone connector to charging socket on the tiller. The approximate driving range on fully charged batteries is up to 37 kilometers (23 miles). The scooter frame is a welded steel construction and includes 2 rear wheels connected by a motor/transaxle with an electromagnetic brake, batteries, 3 front wheels and a tiller to control its turning direction.

When the user activates the throttle lever, the controller receives a signal to release the brakes. With the brakes released, the scooter is allowed to move forward or backwards. When the user releases the throttle lever, the scooter slows to a stop and the brakes are automatically re-engaged. The electromechanical brakes allow the user to stop by letting go of the throttle lever.

The S551 also has fitted to the tiller, an emergency/parking brake which works via a disc brake on to one of the front wheels.

The upholstery of the device complies with ISO 7176-16:2012, resistance to ignition of postural support devices.

The device can be operated on dry, level surfaces composed of concrete, blacktop, or asphalt under normal driving conditions.

5. Indications for Use:

The devices provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.

6. Comparison to the Predicate Device:

The Quingo Classic Power Scooter, S1301 is substantially equivalent to the Merits Transformer, Model S941, (K142162).

The Quingo Toura Power Scooter, S350 is substantially equivalent to the Merits Transformer, Model S941 (K142162).

The Quingo Flyte Power Scooter, S551 is substantially equivalent to the Merits Transformer, Model S941 (K142162).

Below are our “Comparison Tables” comparing the five subject device models to the predicate device:

COMPARISON OF SUBJECT DEVICE (QUINGO CLASSIC) AND PREDICATE DEVICE (Merits Transformer K142162)

ITEMS		SUBJECT DEVICE	PREDICATE DEVICE	Safety & effectiveness of subject device compared to the predicate device.
Brand Name		Classic	Merits Transformer	Different Make
Manufacturer		Advanced Vehicle Concepts Ltd	Merits Health Products Co., Ltd.	Same Manufacturer
Model Number		S1301	S941	Different Model
510K No		K170634	K142162	Different Submission
Series		Power Mobility	Power Mobility	Same

		Scooter Series	Scooter Series	
Indications for Use		The devices provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.	The devices provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.	Same Intended use and target population
Warranty		1 Year	1 Year	Same
Product Code		INI	INI	Same
Weight Limit		350 lbs. / 159 Kg	350 lbs. / 159 Kg	Same Carrying Capacity
Electronics Controller		Dynamics Rhino 2 DS70C	Dynamics Rhino 2 DS120	Same type with different volume controllers
Motor		DC 24V, 250 W	DC 24V, 400 W	Smaller Motor (top speed is less on subject device)
Footplates		Aluminum Adjustable Footplates	ABS	Individual Adjustable footplates ideal to stretch out legs
Suspension	Front	Front Lever Arm Coil Spring	Integral Lever Arm Coil Springs	Same
	Rear	Rear Independent Coil Spring	Independent Coil Springs	Same
Back Upholstery		Fabric	Fabric	Same Material
Batteries	Quantity	2	2	Same Quantity
	Type	12V, 35Ah	12V, 50Ah	Smaller Capacity
Patient Contacting Materials	Seat	Vinyl Fabric	Vinyl Fabric	Same
	Hand Grip	Rubber	Rubber	Same
	Seat Belt	Steel/ ABS/ Polyester Fabric	N/A (No Seat Belt)	Additional Safety Feature
Overall Dimensions	Overall Length	1220mm / 48"	1300mm / 51.2"	Smaller Length
	Overall Width	640mm / 25"	686mm / 27.2"	Smaller width
	Overall Height	900mm / 36"	1245mm / 49"	Lower in overall height
Armrest Types		Removable & Flip-backward	Removable & Flip-backward	Same
Frame		Steel Frame	Steel Frame	Same

Seat Dimensions	Seat Width	457mm / 18"	470mm / 18"	Same
	Seat Height (From Ground)	710mm / 28"	635-685mm / 25-27"	Higher Seating position
	Seat Depth (Actual)	400mm / 15.7"	400mm / 16"	Marginally Smaller Depth
	Seat Height (From Deck)	450-550mm / 18-22"	430-480mm / 17-19"	Higher Seating position
Wheels	Front	10" Pneumatic Tires	12" Pneumatic Tires	Smaller size
	Front (2 x Outer Wheels)	7" Pu Tires	N/A	Extra (5 Wheel design)
	Rear (Drive Wheels)	10" Pneumatic Tires	12" Pneumatic Tires	Smaller size
Turning Radius		1070mm / 42"	1670mm / 65.7"	Smaller Radius making it easier to maneuver
Ground Clearance		127mm / 5"	90mm / 3.5"	Larger clearance
Kerb Climbing Ability		76mm / 3"	100mm / 4"	Slightly less kerb climbing ability
Scooter Weight	Total Unladen	220 lbs. / 100 Kg	118kg / 260 lbs.	Lower Weight
	Without Batteries	170.2 lbs. / 77.2 Kg	84kg / 185 lbs.	Lower Weight
Maximum Speed		4 Mph / 6.4 Kph	7.5 mph / 12 Kph	Less Speed
Incline / Gradient		12 Degrees	10 Degrees	Safer Slope
Range (upto)		23 Miles / 37 Kilometers	25 Miles / 40 Kilometers	Slightly smaller range
Battery Charger	Type	External (off-board) Charger	External (off-board) Charger	Same manufacture
	Voltage Output	24 VDC, 5Ah	24 VDC, 5Ah	Same type, higher ampage
	Model	HP8204-5A	HP8204B-5A	Same Manufacturer

**COMPARISON OF SUBJECT DEVICE (QUINGO Toura) AND PREDICATE DEVICE
(Merits Transformer K142162)**

ITEMS		SUBJECT DEVICE	REFERENCE DEVICE	Safety & effectiveness of subject device compared to the Reference device.
Brand Name		Toura 2	Merits Transformer	Different Make
Manufacturer		Advanced Vehicle Concepts Ltd	Merits Health Products Co., Ltd.	Same Manufacturer
Model Number		S350	S941	Different Model
510K No		K170634	K142162	Different Submission
Series		Power Mobility Scooter Series	Power Mobility Scooter Series	Same
Indications for Use		The devices provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.	The devices provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.	Same Intended use and target population
Warranty		1 Year	1 Year	Same
Product Code		INI	INI	Same
Weight Limit		485 lbs. / 220 Kg	350 lbs. / 159 Kg	Heavier Carrying/ User Weight Capacity
Electronics Controller		Dynamics Rhino 2 DS160	Dynamics Rhino 2 DS120	Same type with different volume controllers
Motor		DC 24V, 650 W	DC 24V, 400 W	Larger Power
Footplates		Aluminum Adjustable Footplates	ABS	Individual Adjustable footplates
Suspension	Front	Integral Lever Arm Coil Springs	Integral Lever Arm Coil Springs	Same
	Rear	Independent Coil Springs	Independent Coil Springs	Same
Back Upholstery		Fabric	Fabric	Same Material
Batteries	Quantity	2	2	Same Quantity
	Type	12V, 100Ah	12V, 50Ah	Larger Capacity

Patient Contacting Materials	Seat	Vinyl Fabric	Vinyl Fabric	Same
	Hand Grip	Rubber	Rubber	Same
	Seat Belt	Steel / ABS / Polyester Fabric	N/A (No Seat Belt)	Additional Safety Feature
Overall Dimensions	Overall Length	1390mm / 54"	1300mm / 51.2"	Larger Length
	Overall Width	670mm / 26.4"	686mm / 27.2"	Smaller Width
	Overall Height	1430 / 56.3"	1245mm / 49"	Higher Seating position
Armrest Types		Removable & Flip-backward	Removable & Flip-backward	Same
Frame		Steel Frame	Steel Frame	Same
Seat Dimensions	Seat Width	540mm / 21.3"	470mm / 18"	Larger Width
	Seat Height (From Ground)	720-790mm / 28.3-33.1"	635-685mm / 25-27"	Higher Seating position
	Seat Depth (Actual)	470mm / 18.5"	400mm / 16"	Larger Depth
	Seat Height (From Deck)	520-590m / 20.5-23.2"	430-480mm / 17-19"	Higher Seating position
Wheels	Front	10" Pneumatic Tires	12" Pneumatic Tires	Smaller size, same type
	Front (2 x Outer Wheels)	9" Pu Tires	N/A	Extra (5 Wheel design)
	Rear (Drive Wheels)	12" Pneumatic Tires	12" Pneumatic Tires	Smaller size, same type
Turning Radius		1320mm / 52"	1670mm / 65.7"	Smaller turning circle
Ground Clearance		155mm / 6.1"	90mm / 3.5"	Larger clearance
Kerb Climbing Ability		100mm / 4"	100mm / 4"	Same
Scooter Weight	Total Unladen	361.3 lbs. / 163.9 Kg	118kg / 260 lbs.	Larger Weight
	Without Batteries	216.7 lbs. / 98.3 Kg	84kg / 185 lbs.	Larger Weight

Maximum Speed		6 Mph / 12.9 Kph	7.5 mph / 12 Kph	Larger speed
Incline / Gradient		12 Degrees	10 Degrees	Safer Slope
Range (upto)		55 Miles / 88 Kilometers	25 Miles / 40 Kilometers	Larger range
Battery Charger	Type	External (off-board) Charger	External (off-board) Charger	Same
	Voltage Output	24 VDC, 8Ah	24 VDC, 5Ah	Same type, higher ampage
	Model	4C24080A	HP8204B-5A	Different type

COMPARISON OF SUBJECT DEVICE (QUINGO FLYTE) AND PREDICATE DEVICE (Merits Transformer K142162)

ITEMS		SUBJECT DEVICE	PREDICATE DEVICE	Safety & effectiveness of subject device compared to the predicate device.
Brand Name		Flyte	Merits Transformer	Different Make
Manufacturer		Advanced Vehicle Concepts Ltd	Merits Health Products Co., Ltd.	Same Manufacturer
Model Number		S551	S941	Different Model
510K No		K170634	K142162	Different Submission
Series		Power Mobility Scooter Series	Power Mobility Scooter Series	Same
Indications for Use		The devices provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.	The devices provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.	Same Intended use and target population
Warranty		1 Year	1 Year	Same
Product Code		INI	INI	Same

Weight Limit		350 lbs. / 159 Kg	350 lbs. / 159 Kg	Same Carrying/ User Weight Capacity
Electronics Controller		Dynamics Rhino 2 DS90	Dynamics Rhino 2 DS120	Same type with different volume controllers
Motor		DC 24V, 250 W	DC 24V, 400 W	Less Power due to lower max speed on the Subject device
Footplates		Aluminum Adjustable Footplates	ABS	Individual Adjustable footplates
Suspension	Front	N/A	Integral Lever Arm Coil Springs	No suspension on subject device
	Rear	N/A	Independent Coil Springs	No suspension on subject device
Back Upholstery		Fabric	Fabric	Same Material
Batteries	Quantity	4	2	Greater Quantity
	Type	12V, 22Ah	12V, 50Ah	Lower amp of batteries in subject. Total amps is subject is 88amp against 100amps in predicate
Patient Contacting Materials	Seat	Vinyl Fabric	Vinyl Fabric	Same
	Hand Grip	Rubber	Rubber	Same
	Seat Belt	Steel/ ABS/ Polyester Fabric	N/A (No Seat Belt)	Additional Safety Feature
Overall Dimensions	Overall Length	1100mm / 43.3"	1300mm / 51.2"	Smaller Length - more maneuverable
	Overall Width	590mm / 23.2"	686mm / 27.2"	Smaller Width - more maneuverable
	Overall Height	1010mm / 39.8"	1245mm / 49"	Smaller in Length to assist maneuverability
Armrest Types		Removable & Flip-backward	Removable & Flip-backward	Same
Frame		Steel Frame	Steel Frame	Same
Seat Dimensions	Seat Width	410mm / 16"	470mm / 18"	Smaller Width
	Seat Height (From Ground)	710mm / 28"	635-685mm / 25-27"	Higher Seating position

	Seat Depth (Actual)	380mm / 14.9"	400mm / 16"	Smaller Depth
	Seat Height (From Deck)	500mm / 19.7"	430-480mm / 17-19"	Higher Seating position
Wheels	Front	10" Pneumatic Tires	12" Pneumatic Tires	Smaller size
	Front (2 x Outer Wheels)	7" Pu Tires	N/A	Extra (5 Wheel design)
	Rear (Drive Wheels)	10" Pneumatic Tires	12" Pneumatic Tires	Smaller size
Turning Radius		1020mm / 40.2"	1670mm / 65.7"	Smaller turning Radius
Ground Clearance		127mm / 5"	90mm / 3.5"	Larger ability
Kerb Climbing Ability		76mm / 3"	100mm / 4"	Slightly less clearance
Scooter Weight	Total Unladen	257 lbs / 116.5 Kg	118kg / 260 lbs	Lower Weight
	Without Batteries	N/A	84kg / 185 lbs	Still Lower on weight
Maximum Speed		4 Mph / 6.4 Kph	7.5 mph / 12 Kph	Lower max speed
Incline / Gradient		6 Degrees	10 Degrees	Smaller angle
Range (upto)		23 Miles / 37 Kilometers	25 Miles / 40 Kilometers	Slightly less range
Battery Charger	Type	External (off-board) Charger	External (off-board) Charger	Same
	Voltage Output	24 VDC, 5Ah	24 VDC, 5Ah	Same type
	Model	HP8204-5A	HP8204B-5A	Same Manufacturer

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the subject device in the intended environment of use is supported by testing that was conducted in accordance with the FDA July 26, 1995 Draft, Reformatted 12/18/97, "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorize Three-Wheeled Vehicles".

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was Advanced Vehicle Concepts Ltd.'s conclusion that testing met all relevant requirements of "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorize Three-Wheeled Vehicles".

The following National and International Standards were utilized for testing the subject devices, which established substantial equivalence between the subject devices and the predicate devices:

Performance Standards:

16-195 ISO 7176-1 Third edition 2014-10-01:- Wheelchairs - Part 1: Determination of static stability

16-159 ISO 7176-2 Second edition 2001-06-15:- Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs

16-192 ISO 7176-3 Third edition 2012-12-15:- Wheelchairs - Part 3: Determination of effectiveness of brakes

16-162 ISO 7176-4 Third edition 2008-10-01:- Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range

16-163 ISO 7176-5 Second edition 2008-06-01:- Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space

16-29 ISO 7176-6 Second edition 2001-10-01:- Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs

16-196 ISO 7176-7 First Edition 1998-05-15:- Wheelchairs - Part 7: Measurement of seating and wheel dimensions

16-197 ISO 7176-8 Second edition 2014-12-15:- Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths

16-167 ISO 7176-9: Third edition 2009-11-15:- Wheelchairs - Part 9: Climatic tests for electric wheelchairs

16-164 ISO 7176-10 Second edition 2008-11-01:- Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs

16-190 ISO 7176-11 Second edition 2012-12-01:- Wheelchairs - Part 11: Test dummies

16-25 ISO 7176-13 First edition 1989-08-01:- Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces

16-165 ISO 7176-14 Second edition 2008-02-15:- Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods

16-191 ISO 7176-16 Second edition 2012-12-01:- Wheelchairs - Part 16: Resistance to ignition of postural support devices

16-166 ISO 7176-21 Second edition 2009-04-01:- Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers

16-198 ISO 7176-22 Second edition 2014-09-01:- Wheelchairs - Part 22: Set-up procedures

16-194 ISO 7176-25 First edition 2013-07-15:- Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs

16-187 ANSI RESNA WC-1:2009- American National Standard for Wheelchairs – Volume 1:- Requirements and Test Methods for Wheelchairs (including Scooters) Section 26: Vocabulary

ISO 9001:2008:- Requirements for a quality management system

ISO 13485:2003 + AC: 2007:- Medical devices -- Quality management systems -- Requirements for regulatory purposes

5-40: ISO 14971 Second Edition 2007-03-01:- Medical Devices - Application of Risk Management to Medical Devices. (General I (QS/RM))

BS EN 1041:2008:- Information supplied by the manufacturer of medical devices

BS EN 12184:2014:- Electrically powered wheelchairs, scooters and their chargers. Requirements and test methods

BS EN 12182:1999 Technical aids for disabled persons. General requirements and test methods

IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests. (General II (ES/EMC))

EN 55011:2007 Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement

BS EN 1021-1/2: 2006 Fire Test to Upholstered Furniture

8. Discussion of Clinical Tests Performed:

Not applicable as there are no new indications for use which must be supported by a clinical data.

9. Software Information:

Software validation was conducted in accordance with a major level of concern designation in accordance with the FDA November 2005 document "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices".

10. Conclusions:

Conclusions drawn from the performance, bench and non-clinical tests demonstrate that the subject devices are as safe, effective and perform as well as the predicate devices.