



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 8, 2017

Agile Distributors LLC
Steven Mahaffy
Corporate Counsel
2283 East Zion Way
Chandler, Arizona 85249

Re: K171256
Trade/Device Name: Quingo Flyte Mobility Scooter
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: April 21, 2017
Received: April 28, 2017

Dear Mr. Mahaffy:

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,

Michael J. Hoffmann -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)

K171256

Device Name

Quingo Flyte Mobility Scooter

Indications for Use (Describe)

The Quingo Flyte is an electric scooter designed to provide transportation to those with mobility limitations such as the disabled or elderly.

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) EXECUTIVE SUMMARY

Submitter's Name: Agile Distributors LLC
A Company incorporated in Arizona (Company Number L-1956314-4)
2283 East Zion Way,
Chandler,
AZ 85249
Tel: (480) 6597180

Contact Name: Steven C Mahaffy

Date Summary Prepared: 15th April 2015 (Modified 2nd August 2016)

Device Names:

Proprietary Name:	Quingo Flyte Mobility Scooter
Model Identity:	S551 (Flyte Configuration)
Common or Usual Name:	Electric Scooter
Classification:	Classification. Class II (performance standards)
Device Code:	INI
Classification Name:	Motorized Three-wheel Vehicle (890.3800)

Predicate Device:

The legally marketed predicate device for substantial equivalence comparison is:

- Kymco EQ 30, manufactured and distributed by Kwang Yang Motor Company Ltd., and cleared under 501(k) K072630

Description of the Device:

The Quingo Flyte Mobility Scooter is a battery powered indoor and outdoor scooter. The vehicle uses a 5 (Five) wheel system comprised of 3 main wheels with two additional wheels to provide additional safety, stability and improved turning ability. Attached to the wheelbase are a padded seat, steering tiller, bars and electronic controls which allow the user to properly direct and control the vehicle.

As the vehicle is battery powered a charging unit is included. To assist with loading and unloading into vehicles for transport an aluminium railing system which fits into most vehicles is provided along with a directly wired electronic control so that no disassembly is required and no heavy lifting by the user is needed.

Intended Use of Device:

The Quingo Flyte is an electric scooter designed to provide transportation to those with mobility limitations such as the disabled or elderly.

Substantial Equivalence

The Intended Use of the predicate device (Kymco ForU EQ30) is 'intended for an indoor/outdoor scooter that provides transportation for disabled or elderly persons limited to a seated position'.

In terms of intended function and general operation this device is very similar to the Quingo Flyte with only minor technical differences that do not present any new questions regarding safe and effective use. Where the units do differ is the provision with the Quingo Flyte of a specific ramp accessory. We believe the provision of this ramp accessory, specifically designed for this unit to maximize safe loading and unloading into vehicles, is a safer option than untested generic ramp accessories that can be purchased for the Predicate and other devices on the open market without any safety or performance testing or FDA approval. The Quingo Flyte, while using the ramp accessory has been safety tested and the results provided with this application. Therefore, we believe the Quingo Flyte is substantially equivalent to this predicate and other legally marketed mobility scooters currently in distribution. See the product comparison table of vehicle features below for further details.

Product Comparison Table.

Device & Predicate Device(s):	<u>K171256</u>	<u>K072630</u>
Manufacturer	Advanced Vehicle Concepts Ltd	Kwang Yang Motor Company Ltd
Model	Quingo Flyte Mobility Scooter	Kymco Super4 4U (EQ30BB)
Framework	Foldable	Rigid
Maximum User Weight	350lbs	330lbs
Length	1110mm	1250
Width	590mm	560mm

Height	1050mm	1250mm
Maximum Speed	6.4 Kph/ 4 mph	8 Kph/ 4.7 mph
Range Per Charge	37 Km/ 23 Miles or 54 Km/ 34 miles	37km or 23.1 miles
Wheel Size	177.8mm (7") & 254mm (10")	255mm (10")
Wheel Type	Solid & Pneumatic	Pneumatic
Heaviest Part	N/A (Vehicle Loads as One Unit)	53lbs/24 Kg
Total Weight Inc. Batteries	256.3lbs	185.7lbs
Batteries	22A x 4 / 22A x 6	36A
Range per Charge	23 miles (4 batteries) 37 miles (6 batteries)	23.1 mi
Charger	240 VAC input, 24V 6 Amp DC output	HP 24V, 5A on-board
Seat Height	515mm	756mm
Lights Fitted	Yes	Yes
Maximum Slope - Degrees (Rear Tip)	6	10
Turning Radius	1020mm (40.2 inches)	1565mm (61.6 inches)
Rated Motor Power	250 Watt, 2 Pole	350 Watt
Input Voltage	24V	24V
Brake System	Intelligent Regenerative Electromagnetic Brake & Hand Brake	Intelligent Regenerative Electromagnetic Brake & Hand Brake
Minimum braking distance - Forward	40 in	48.8 in
Minimum braking distance - Reverse	40 in	Unknown
Ground clearance while occupied	4.72 Inches or 120mm	2 Inches or 51mm
Controller	Rhino 2 DS 90	KYSA 70
Rear Wheel Drive	Sealed Transaxle Direct Drive	Sealed Transaxle Direct Drive
Battery Type	Sealed gel	Lead Acid

Anti Tip Wheels	Yes - Powered Anti-Tip - Anti Curb Trap Wheels	Yes
Suspension	No	Rear only
Operation Mode	Thumb Operated Potentiometer Throttle Control	Thumb Operated Potentiometer Throttle Control
Battery Charger	Automatic Off Board SA	Automatic Off Board SA
Adaptive Footplates	Yes	No
Armrest	Yes - Adjustable	Yes
Tiller	Yes Foldable	Yes Foldable
Front Wheels	7"x2.5" Solid tyres	10"x5" Pneumatic tyres
Rear Wheels	10"x5" Pneumatic tyres	10"x5" Pneumatic tyres
Warning Horn	Yes	Yes
Speed Control	Single Mode - Variable (By potentiometer)	Single Mode - Variable (By potentiometer)
Braking Distance Full Speed (Forward and Backward)	40"	48.8"
Bumpers	Yes. Steel Tube with Spring Suspension	Yes. Steel Tube
Maximum Curb Height	3"	3.14"
Battery Indicator Level	Yes	Yes
Docking Station		
Speed up/down the ramp	1 mph	N/A
Overall weight	83.6 lbs.	N/A
Side ramp weight (each side)	27.8 lbs.	N/A
Center ramp weight	6 lbs.	N/A
Frame weight (including side support arms)	22 lbs.	N/A
Overall length (with supports)	53.2 in	N/A
Folded length	48.5 in	N/A
Overall width	30.3 in	N/A

Height	7.5 in	N/A
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Technological Characteristics:

This device is very similar to the predicate device and other electric scooters that have been cleared under 510(k) in that it comprises of a single drive shaft, regenerative automatic brakes, steering tiller with electronic controls and fire resistant padded seating. The unit, as with most models can be disassembled for transport but in the case of this particular model, accessories in the form of an aluminium rail loading system that can be mounted into certain vehicle types and a physically wired (not wireless) remote control is provided to enable safe loading and unloading of the model without any disassembly or lifting.

Testing Conducted:

Tests listed in the *Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Scooters, and Motorized Three Wheeled Vehicles, July 1995*, were conducted and the results included in the submission. The unit was tested in accordance with ISO 7176 Parts 1-11, 13, 14, 16, 19, 21, 22, 25 & 26 and was found compliant.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

Conclusion:

Review and evaluation of predicate device data and information provided in this 510(k) submission lead us to conclude that this device is substantially equivalent to the predicate device and that neither the device nor supplied accessories create any new safety or performance concerns.