



March 16, 2017

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

Kwang Yang Motor Co., Ltd.
% Mrs. Junnata Chang
No. 35, Wan Hsing Street, San Min Dist.
Kaohsiung 803 Taiwan

Re: K163201
Trade/Device Name: KYMCO EQ10D Scooter
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: February 5, 2017
Received: February 16, 2017

Dear Mrs. Junnata Chang:

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)

K163201

Device Name

KYMCO EQ10D Scooter

Indications for Use (Describe)

The device is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Applicant

Name: KWANG YANG MOTOR CO., LTD.

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Date prepared: Jan. 15, 2017

Device

Trade name: KYMCO EQ10D scooter

Common name: Electrical scooter

Classification name: Motorized three-wheeled vehicle

Medical specialty (Panel): Physical Medicine Device

Regulation number: 890.3800

Product Code: INI

Classification: Class II

Predicate devices

Trade name: KYMCO

Model: EQ 20C

510(k) number: K130940

Manufacture: KWANG YANG MOTOR CO., LTD.

Regulation number: 890.3800

Product Code: INI

Classification: Class II

Intend use of device

It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

Device description:

The EQ10D scooter consists of an un-foldable platform which connects the two front wheels and two rear wheels, an adjustable tiller, two lead acid batteries with an off-board charger, a motor/electromagnetic brake assembly, a electric motor controller and a seat /backrest set.

The patient uses the tiller handle/handlebar for steering and a thumb operated potentiometer throttle control lever located at the top of the tiller to engage and disengage the scooter motion in both the forward and reverse directions. When the throttle control lever is released, the electromagnetic brake will be actuated and the scooter is slow to stop.

This scooter is designed for use on firm, even surfaces such as concrete, asphalt and indoor flooring.

Summary of non-clinical testing

The EQ10D scooter complied with the requirements of ISO 7176-1, ISO 7176-2, ISO 7176-3, ISO 7176-4, ISO 7176-5, ISO 7176-6, ISO 7176-7, ISO 7176-8, ISO 7176-9, ISO 7176-10, ISO 7176-11, ISO 7176-13, ISO 7176-14, ISO 7176-15, ISO 7176-16, ANSI/RESNA WC Vol. 2 Sec. 21, ISO 7176-25, ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 14971.

Statement of substantial equivalence

The EQ10D scooter is substantially equivalent to the EQ 20C (K130940). They have same intended use of a motor driven, indoor and outdoor transportation vehicle to provide mobility to a disabled or elderly person limited to a seated position.

The design and technological characteristics of this device is basically similar to the predicate device chosen. Both are un-foldable scooters and have the same user interface. While there are minor differences between the devices, do not alter the intended use function and use of the device. Moreover, the non-clinical tests and the predicate comparisons demonstrate that these differences in their technological characteristics do not raise any questions as to the safety and effectiveness.

The EQ10D is substantially equivalent to the KYMCO EQ 20C (K130940) manufactured by KWANG YANG MOTOR CO. LTD.. They have same intended use of a motor driven, indoor and outdoor transportation vehicle to provide mobility to a disabled or elderly person limited to a seated position.

The design and technological characteristics of this device is basically similar to the predicate device. They are 4-wheeled scooters with basic conventional rear wheel drive which with free-wheel mode. The motor of both devices is equipped with differential mechanism, which the differential rate is 19.7:1. The anti-tip wheels are equipped

behind the rigid frame of both devices. The power supply of both devices is self-contained lead-acid batteries to provide power that can be recharged by a charger that can be plugged into an AC outlet when the devices are not in use. The horn and foldable armrests are also equipped on both devices.

Both devices have the same user interface, the patient uses the foldable tiller handle/handlebar for steering and a thumb operated potentiometer throttle control lever located at the top of the tiller to engage and disengage the scooter motion in both the forward and reverse directions. When the throttle control lever is released, the electromagnetic brake will be actuated and the scooter is slow to stop. The speed mode of the both devices was single mode and the speed control dial can control the maximum speed. Both seats of the devices are equipped with removable flip-up armrest and there is no headrest on backrest. Seat cushions and backrests of both devices used the same materials, which is PU foam covered by nylon fabric cloth. The seat, seat cushion, backrest, handlebar and throttle control lever of the device will contact to the patient. The materials of the patient contacting parts used for the EQ10D scooter and predicate device are exactly same and no additional processing different from predicate device, so no new safety and efficacy concerning.

The predicate device is equipped with head light, tail light, signal light and warning light, which EQ 10D does not. There are warn labels in the EQ10D user manual that remind users do not ride the scooter at night in case of danger, because the scooter does not equipped head light, tail light, signal light and warning light, so do not raise any questions as to the safety.

The main difference for the two devices is the rated power of the used batteries, the rated power of the motor, battery charger type, lights and the maximum speed. While there are minor differences between the devices including dimensions, wheels size and pre-charging distance, do not alter the intended use function and use of the device.

Moreover, the non-clinical tests and the predicate comparisons demonstrate that these differences in their technological characteristics do not raise any questions as to the safety and effectiveness.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, KWANG YANG MOTOR CO., LTD. concludes that, EQ10D scooter is substantially equivalent to predicate devices as described herein.

The substantial equivalence comparison of the EQ10D and EQ 20C (K130940)

	EQ 20C (K130940)	EQ10D	Comparison to the predicate device
Indications for use	They are motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.		Same indications for use
Maximum load capacity	127 kg (280 lbs)	125 kg (275 lbs)	Smaller load capacity
ISO 7176-5			
Overall length	1080 mm (43.5")	1020 mm (40.2")	Smaller overall length
Overall width	520 mm (20.5")	377 ~ 500 mm (14.8 ~ 19.7")	Smaller overall width
Handgrip height	88 cm(34.6")	89 cm(35")	Larger handgrip height
Stowage length	106 cm(41.7")	102 cm(40.2")	Smaller stowage length
Stowage width	510 mm(20.1")	487 mm(19.2")	Smaller stowage width
Stowage height	450 mm(17.7")	940 mm(37")	Larger stowage height
Rising	150 mm(5.9")	105 mm(4.1")	Smaller rising
Total mass	with battery : 55.5 kg (122 lbs) without battery : 45 kg(99 lbs)	with battery : 43 kg(94.6 lbs) without battery : 33 kg (72.6 lbs)	Lighter mass
Mass of heaviest part	20.5 kg (45.2 lbs) body frame with motor	14 kg(30.8 lbs) body frame with motor	Lighter mass of heaviest part
Pivot width	250 cm(98.4")	150.5 cm(59.3")	Smaller pivot width
Reversing width	160 cm(63")	233 cm(91.7")	Larger reversing width

(Continuous)

The substantial equivalence comparison of the EQ10D and EQ 20C (K130940)

	EQ 20C (K130940)	EQ10D	Comparison to the predicate device
Turning diameter	250 cm(98.4")	242 cm(95.2")	Smaller turning diameter
Ground clearance	60 mm(2.4")	50 mm(2")	Smaller ground clearance
Required width of angled corridor	120 cm(47.2")	106.5 cm(41.9")	Smaller required width of angled corridor
Required doorway entry depth	106 cm(41.7")	60 cm(23.6")	Smaller required doorway entry depth
Required corridor width for side opening	190 cm(74.8")	110 cm(43.3")	Smaller required corridor width for side opening
ISO 7176-7			
Seat plane angle	5°	2°	Smaller seat plane angle
Effective seat depth	350 mm(13.8")	483 mm (19")	Larger effective seat depth
Seat width	350 mm(13.8")	400 mm (15.7")	Larger seat width
Effective seat width	307 mm ~ 430 mm (12" ~ 17")	327 mm ~ 450 mm (12.8" ~ 18")	Larger effective seat width
Seat surface height at front edge	440 mm~516 mm (17.3"~20.3")	445 ~ 521 mm (17.5" ~ 20.5")	Larger seat surface height at front edge
Back support angle	12°	15°	Larger back support angle
Back support height	395 mm(15.6")	290 mm(11.4")	Smaller back support height
Back support width	350 mm(13.8")	400 mm (15.7")	Larger back support width

(Continuous)

The substantial equivalence comparison of the EQ10D and EQ 20C (K130940)

	EQ 20C (K130940)	EQ10D	Comparison to the predicate device
Foot support to seat distance	345 ~ 421 mm (13.6" ~ 16.6")	370 ~ 446 mm (14.6" ~ 17.6")	Both devices are adjustable
Foot support clearance	70 mm(2.8")	50 mm(2")	Smaller foot support clearance
Arm support height	155 mm(6.1")	180 mm(7.1")	Larger arm support height
Front of arm support to back support	250 mm(9.8")	350 mm(13.8")	Larger front of arm support to back support
Arm support length	260 mm(10.2")	300 mm(11.8")	Larger arm support length
Arm support width	50 mm(2")		Same arm support width
Arm support angle	0°		Same arm support angle
Distance between arm supports	420 mm(16.5")	377 mm ~ 500 mm (14.8" ~ 19.7")	Distance between arm supports is adjustable

(Continuous)

The substantial equivalence comparison of the EQ10D and EQ 20C (K130940)

	EQ 20C (K130940)	EQ10D	Comparison to the predicate device
Horizontal location of the wheel axle	219 mm(8.6")	283 mm(11.4")	Larger horizontal location of the wheel axle
Vertical location of the wheel axle	284 mm(11.2")	277 mm(10.9")	Smaller vertical location of the wheel axle
Material	PU foam covered by nylon fabric cloth		Same materials
Seat			
Seat cushion			
Backrest			
Differential mechanism	Differential rate: 19.7 : 1		Same differential mechanism
Free-wheel mode	Yes		Both devices have free- wheel mode
Speed mode	Single mode, Variable		Same speed mode
Lights			
Head/Tail lights	Yes	No	Without head/tail lights
Signal light	Yes	No	Without signal light
Warning light	Yes		Both devices have warning light
Horn	Yes		Both devices have horn

(Continuous)

The substantial equivalence comparison of the EQ10D and EQ 20C (K130940)

	EQ 20C (K130940)	EQ10D	Comparison to the predicate device
Anti-tip wheels	Yes		Both devices have anti-tip wheels
Operation mode	Thumb operated potentiometer throttle control lever		Same operation mode
Armrest	Removable flip-up armrest		Same type armrest
Tiller foldable	Yes		Same type tiller
Headrest	No		Both device without headrest
Motor			
Rated power	250 W	270 W	Larger rated power
Input voltage	DC 24V		Same input voltage
Amount	1 Pc		Same amount
Brake system	Intelligent regenerative electromagnetic brake and hand brake		Same type brake system
Controller	PG S-Drive, 45A		Same controller
Rear wheel drive	Sealed transaxle direct drive		Same type drive
Braking distance(at max speed)	Forward:1.0 m (39.4")	Forward: 1.1 m (43.3")	Larger braking distance
Per-charge distance	Up to 21 km (13 miles)	Up to 16 km (10 miles)	Smaller per-charge distance
Maximum speed	Up to 6.5 km/h (4.1 mph) , variable	Up to 6.4 km/hr (4 mph), variable	Smaller max. speed
Maximum curb height	50 mm (2")		Same maxi. curb height
Suspension	Front: No, Rear: Yes		Same

(Continuous)

The substantial equivalence comparison of the EQ10D and EQ 20C (K130940)

	EQ 20C (K130940)	EQ10D	Comparison to the predicate device
Battery			
Type	Lead-acid		Same type batteries
Rated power	22 Ah	24 Ah	Larger rated power
Output voltage	24 VDC		Same output voltage
Amount	DC 12V x 2 Pcs		Same amount
Battery level indicator	Yes		Both have battery level indicator
Charger			
Type	on-board, Automatic Type	off-board, Automatic Type	Different type
Input power requirement	115-230 VAC		Same input power
Output voltage / current	DC 24V / 5A	DC 24V / 2A	Same output voltage Smaller output current
Front wheels			
Diameter	70 mm/62.5 mm – 100 mm(2.8"/2.5"-4")	7.5" × 2.35"	Larger diameter
type	non-pneumatic tires		Same type tires
Material	Polyurethane (PU)		Same material
Amount	2		Same amount

(Continuous)

The substantial equivalence comparison of the EQ10D and EQ 20C (K130940)

	EQ 20C (K130940)	EQ10D	Comparison to the predicate device
Rear wheels			
Diameter	70 mm/62.5 mm – 100 mm(2.8"/2.5"-4")	7.5" × 2.35"	Larger diameter
type	non-pneumatic tires		Same type tires
Material	Polyurethane (PU)		Same material
Amount	2		Same amount