K130940

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.
Address: No. 35, Wan Hsing Street, San Min Dist., 803, Kaohsiung, Taiwan
Registration number: 3003851898
Contact person: Yen, Wen Hsi
Phone: +886-7-3822526
Fax: +886-7-3825834
e-mail: yen@mail.kymco.com

OCT 07 2013

Date prepared: Aug. 15, 2013

Device

Trade name: KYMCO
Model: EQ 20C 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 30
510(k) number: K072630
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 EQ 20C 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 on-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.

Summary of non-clinical testing

The EQ 20C scooter complied with the requirements of ANSI/RESNA WC Vol. 1 Sec. 7 and Sec 8, ANSI/RESNA WC Vol. 2 Sec. 21, ISO 7176-1, ISO 7176-2, ISO 7176-3, ISO 7176-4, ISO 7176-5, ISO 7176-6, ISO 7176-9, ISO 7176-10, ISO 7176-11, ISO 7176-13, ISO 7176-14, ISO 7176-15, ISO 7176-16, ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 14971, EN 61000-4-2, EN 61000-4-3, EN 61000-4-8, and CISPR 11.

Statement of substantial equivalence

The EQ 20C scooter is substantially equivalent to the EQ 30 (K072630). 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.

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, EQ 20C scooter is substantially equivalent to predicate devices as described herein.

The substantial equivalence comparison of the EQ 20C and EQ 30 (K072630)

	EQ 20C	EQ30 (K072630)
Intended 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.	
Maximum load capacity	127 kg (280 lbs)	150 kg (330 lbs)
Overall dimension		
Height	921 mm (36.3")	1250 mm (49.2")
Length	1080 mm (43.5")	1240 mm (48.8")
Width	520 mm (20.5")	560 mm (22")
Seat Overall dimension		
Height	550 mm (21.7") (from ground)	756 mm (29.8")
Width	427 mm (16.8")	455 mm (17.9")
Depth	350 mm (13.8")	400 mm (15.7")
Seat / Seat cushion / Backrest		
Material	PU foam covered by nylon fabric cloth	
Motor		
Rated power	250 W	350 W
Input voltage	DC 24V	
Amount	1 Pc	
Brake system	Intelligent regenerative electromagnetic brake and hand brake	
Controller	PG S-Drive, 45A	KYSA 70
Differential mechanism	Differential rate: 19.7 : 1	
Rear wheel drive	Sealed transaxle direct drive	

(Continuous) The substantial equivalence comparison of the EQ 20C and EQ 30 (K072630)

	EQ 20C	EQ30 (K072630)
Free-wheel mode	Yes	
Braking distance	Forward:1.0 m (39.4") at max speed	Forward: 1.24 m (48.8") at max speed
Net weight with battery	55.5 kg (122 lbs)	84.4 kg(185.7 lbs)
Slope grade ability	8 degree	10 degree
Per-charge distance	Up to 21 km (13 miles)	Up to 37 km (23.1 miles)
Maximum speed	Up to 6.5 km/h (4.1 mph) , variable	Up to 8 km/hr (4.7 mph), variable
Speed mode	Single mode, Variable	
Turning radius	1200 mm (47.2")	1565 mm (61.6")
Maximum curb height	50 mm (2")	80 mm (3.14")
Suspension	Front: No, Rear: Yes	
Head/Tail lights **Signal light**	Head/tail lights and signal lights of the EQ 20C, and EQ 30 scooters have the same functions, but only the styles are different.	
Warning light	Yes	
Horn	Yes	
Anti-tip wheels	Yes	
Operation mode	Thumb operated potentiometer throttle control lever	
Armrest	Yes, Foldable	
Tiller foldable	Yes	
Headrest	No	Yes
Height adjustable	No	Yes

(Continuous) The substantial equivalence comparison of the EQ 20C and EQ 30 (K072630)

	EQ 20C	EQ30 (K072630)
Battery		
Type	Lead-acid	
Rated power	22 Ah	31 Ah
Output voltage	24 VDC	
Amount	DC 12V x 2 Pcs	
Battery level indicator	Yes	
Charger		
Type	on-board, Automatic Type	
Input power requirement	115-230 VAC	
Output voltage / current	DC 24V / 5A	
Front wheels		
Diameter	70 mm/62.5 mm – 100 mm(2.8"/2.5"-4")	250 mm x 125 mm(10" x 5")
type	non-pneumatic tires	
Material	Polyurethane (PU)	
Amount	2	
Rear wheels		
Diameter	70 mm/62.5 mm – 100 mm(2.8"/2.5"-4")	250 mm x 125 mm(10" x 5")
type	non-pneumatic tires	
Material	Polyurethane (PU)	
Amount	2	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 7, 2013

Kwang Yang Motor Co., Ltd.
c/o Mrs. Junnata Chang
16F-2(16A), No. 462, Sec. 2, ChongDe Rd.
Beitun Dist. Taichung
CHINA (Taiwan) 406

Re: K130940
Trade/Device Name: Kymco EQ 20C scooter
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: Class II
Product Code: INI
Dated: August 15, 2013
Received: August 22, 2013

Dear 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting 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): K130940

Device Name: KYMCO EQ 20C SCOOTER

Indications For Use:

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

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Victor Krauthamer -S
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