

K072027

AUG 20 2007



KWANG YANG MOTOR CO., LTD.

No. 35, Wan Hsing Street, San Min Dist., 803, Kaohsiung, Taiwan

TEL: +886-7-3822526 FAX: +886-7-3825834

510(k) Summary

Device

Trade name: *ForU* KV10HB powered wheelchair

Common name: **Powered wheelchair**

Classification name: **Powered wheelchair**

Medical specialty (Panel): **Physical Medicine Device**

Regulation number: **890.3860**

Product Code: **ITI**

Classification: **Class II**

Predicate devices

CWD01 (K062888) / EMG Technology Co. Ltd.

Intend use of device

ForU KV10HB powered wheelchair is intended for an indoor/outdoor power wheelchair that provides transportation for disabled or elderly persons limited to a seated position.

Device description:

The *ForU* powered wheelchair is an indoor/outdoor powered wheelchair that is battery operated. The design of this wheelchair is basically similar to other powered wheelchairs that are already on the market. But the *ForU* KV10HB is kind of a new class of lightweight powered wheelchair. By providing a powered wheelchair that breaks down into two manageable components (seat frame, body frame with motors and battery pack), a user can have a more practical alternative when traveling long distances by bus, train, etc.

Substantial equivalence:

The *ForU* KV10HB powered wheelchair is substantially equivalent to the **CWD01 (K062888)** manufactured by **EMG Technology Co. Ltd.**

There are minor differences in performance specifications of the powered wheelchairs, these differences do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness. Therefore, **KWANG YANG MOTOR CO., LTD.** believes that the *ForU* KV10HB powered wheelchair is substantially equivalent to legally marketed devices currently in commercial distribution.



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The substantial equivalence comparison of the *ForU* KV10HB and CWD01

	<i>ForU</i> KV10HB	CWD01 (K062888)
Intended use	It is motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to disabled or elderly persons limited to a seated position.	It is intended for medical purposes to provide mobility to persons restricted to a sitting position.
Maximum loading	165 kg (350lbs)	136 kg (300 lbs)
Overall height	1140 mm (44.9")	1130 mm (44.5")
Overall length	1032 mm (40.6")	900 mm (35.4")
Overall width	644mm (25.4")	650 mm (25.6")
Seat overall height	600 mm (23.6")	
Seat overall width	800 mm (31.5")	18"
Seat overall depth	500 mm (19.7")	
Seat overall weight	21 kg (46.2 lbs)	
Motor output	DC 24V, 200 W, 2 Pcs	260W x DC24V x 2Pcs
Controller	PG VR2	Dynamic Shark
Rear wheel drive		Sealed transaxle direct drive
Battery	Gel/Seal Lead-Acid 12V x 50AH x 2PCs	Lead-Acid 12Vx35AHx2PCs
Charger	DC 24V 5 AMP (Automatic Type) on-board	DC 24V 5A, off-board
Front/Rear wheel	6" Solid tire x 2 PCs	6" pneumatic tire x 2 PCs
Middle wheel	12.8" Solid tire x 2 PCs	10" PU foaming tire x 2 PCs



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(Continuous) The substantial equivalence comparison of the ForU KV10HB and CWD01

	ForU KV10HB	CWD01 (K062888)
Armrest	Fixed	Removable
Break system	Intelligent regenerative electromagnetic brake	
Braking distance	Forward: 0.9 m(35.4") at max speed	
Net weight w battery	98 kg (215.6 lbs)	83.5kg (183.7 lbs) includes batteries
Heaviest piece weight	44 kg (96.8 lbs.) body frame with motor	
Slope grade ability	10 degree	12 degree
Per-charge distance	Up to 37 km (23.1 miles)	40 km (24 miles)
Maximum speed	Up to 6.5 km/hr (4.1 mph), variable	5 km/h (3.2 mph)
Turning radius	515 mm (20.3")	
Maximum curb height	80 mm (3.147")	
Suspension	Front/Rear: No, Middle: Yes	Cross brace
Horn		Yes



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kwang Yang Motor Co., Ltd.
% Mr. Yen, Wen Hsi
No. 35, Wan Hsing Street
San Min Dist., 803
Kaohsiung, Taiwan

AUG 20 2007

Re: K072027
Trade/Device Name: ForU KV10HB Powered Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: July 20, 2007
Received: July 24, 2007

Dear Mr. Yen, Wen Hsi:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

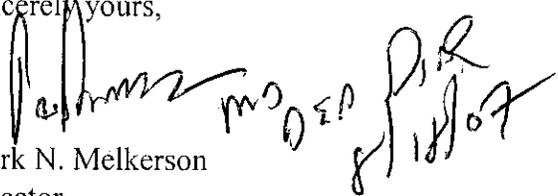
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

Page 2 – Mr. Yen, Wen Hsi

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a date '8/18/07' written to the right of the signature.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Device descriptive information
3.1 Statement of indication for use

Statement of Indications for use

510(k) Number (if known): _____

Device Name: *ForU* KV10HB

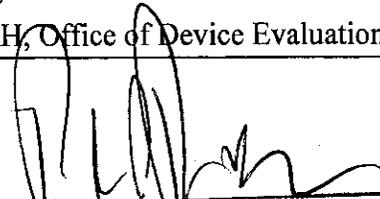
Indications for use:

The *ForU* KV10HB powered wheelchair is motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to disabled or elderly persons limited to a seated position.

Prescription Use _____ Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) AND/OR (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number 12072027

(Posted November 13, 2003)