



**COMFORT ORTHOPEDIC CO., LTD.**

[www.comfort.com.tw](http://www.comfort.com.tw)

No.120,Nan Shiang Tsuen,Shoei Shang Shiang,Chia-yi,Taiwan,R.O.C.608

TEL : 886-5-2892093

FAX : 886-5-2890070

**“ 510(k) SUMMARY ”**

DEC - 4 2006

Submitter's Name: **COMFORT ORTHOPEDIC CO., LTD.**

N0. 120, NAN SHIANG TSUEN, SHOEI SHANG SHIANG, CHIA-YI,  
TAIWAN, ROC

Date summary prepared:

September 29, 2006

Device Name:

Proprietary Name: COMFORT SCOOTER, LY-EW406  
Common or Usual Name: Electric Scooter  
Classification Name: Motorized 3-Wheeled Vehicle, Class II,  
21 CFR 890.3800

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The COMFORT SCOOTER, LY-EW406 is an indoor / outdoor Electric Scooter that is battery operated. It has a base with four-wheeled with a seat. The movement of the Wheelchair is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with an onboard battery charger.

Performance Testing:

EMC Report ANSI / RESNA WC/Vol.2-1998, CISPR 11: 1990, EN61000-3-2: 1995, IEC61000-3-3: 1995 (Electrically Powered Wheelchairs, controller, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

COMFORT AGILE SCOOTER LY-EW303 (K022369)



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Summary for substantial equivalence comparison:

The intended uses, the load weight limit 265 lbs, electronic controller, back upholstery and armrest types, and warranty period between the new device LY-EW303 and the predicate device LY-EW302 are the same. Especially the electronic controller and recharge between two devices are all passed by the UL certificated. Thus the same safety level for the two devices is assured.

The major difference existing is the new device is more agile than the predicate device. Besides the overall dimension, the size of tires, and the weight are differences between the two devices. The overall appearance differences are not safety aspect. So the new device is substantially equivalent to the predicate devices in this aspect.

The maximum speed is 4.2 mph for the new device and 4.0 mph for the predicate device that are also under the 6 miles maximum speed limited. Those speeds can be continuous adjusted by the throttle tiller. The operators can set the adequate speed according to their feeling and need, and the maximum speed differences do not mean any performance differences. They are substantially equivalent.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Comfort Orthopedic Co., Ltd.  
% Dr. Ki-Men Jen  
Roc Chinese European Industrial Research Society  
No. 120, Nan Shiange Tsuen,  
Shoei Shang Shiang,  
Chia-yi,  
Taiwan, R.O.C. 608

DEC - 4 2006

Re: K063030  
Trade/Device Name: Comfort Scooter, LY-EW406  
Regulation Number: 21 CFR 890.3800  
Regulation Name: Motorized three-wheeled vehicle  
Regulatory Class: Class II  
Product Code: INI  
Dated: September 29, 2006  
Received: October 3, 2006

Dear Dr. Jen:

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.

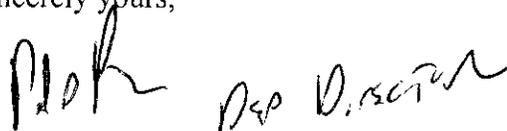
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 – Dr. Jen Ki-Men

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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Handwritten signature of Mark N. Melkerson in black ink.

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

Enclosure



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## Indications for Use

510 (K) Number ( If Known ): K063030

Device Name: COMFORT SCOOTER, LY-EW406

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Prescription Use \_\_\_\_\_

AND/OR

Over-The-Counter Use √

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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

Concurrence of  CDRFI, Office of Device Evaluation (ODE)

**(Division Sign-Off)**

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

Page 1 of 1

510(k) Number K063030