

COMFORT ORTHOPEDIC CO., LTD.

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

K072712

OCT 31 2007

“ 510(k) SUMMARY ”

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

NO. 120, NAN SHIANG TSUEN, SHOEI SHANG SHIANG, CHIA-YI, 608,
TAIWAN, ROC

Date summary prepared:

September 20, 2007

Device Name:

Proprietary Name: COMFORT SCOOTER, LY-EW408
Common or Usual Name: Electric Scooter
Classification Name: Motorized 4-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-EW408 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 SCOOTER LY-EW415 (K063032)

Summary for substantial equivalence comparison:

The overall dimensions and visual appearance are similar, and the dimensions for the new device are smaller than that of the predicate device. The device of the smaller dimensions can be fitted into most of the ordinary car trunk. Thus the new device may be fitted into smaller car trunk. It certainly the new device has more convenient during moving and turning.

The electronic systems between two devices are the same suppliers, and all passed by the UL certificated, for instance the **electronic controller**, **batteries**, and **recharge**. Besides, the back upholstery is the same material, and also passed the resistance ignition test by SGS. Moreover, the suspension of cross brace, footplates, incline degree 12°, armrest type, and warranty are all the same. The safety and performance functions of two systems are assured and validated. They are substantially equivalent.

The maximum speed is 1.0 mph difference for the two devices. The throttle tiller can continuously adjust the speeds. The operators can set the adequate speed according to their feeling and need, i.e., outdoor or indoor, and the maximum speed differences do not mean any performance differences. They are substantially equivalent.

The battery chargers types are almost the same; only for the output electric current is 4A for the new device and 5A for the predicate device. The current differences lead to the charging period differences or arise from the different battery capacity, not related with safety aspect.

Based on the above the information and the analysis, we know that the subject device and the predicate device have the same intended use, the same technological aspects and only minor differences exist. We believe that FDA can decide the subject device and the predicate device are substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Comfort Orthopedic Co., LTD.
% ROC Chinese European Industrial Research Society
Dr. Jen, Ke-Min
No. 58 Fu-Chiun Street
Hsin-Chu City, Taiwan, ROC

SEP 28 2007

Re: K072712
Trade/Device Name: Comfort Scooter, LY-EW 408
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: September 20, 2007
Received: September 25, 2007

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, Ke-Min

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 long horizontal flourish extending to the right.

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

TEL : 886-5-2892093

FAX : 886-5-2890070

Indications for Use

510 (K) Number (If Known): K

Device Name: COMFORT ELECTRIC SCOOTER, LY-EW408

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 CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

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

Page 1 of 1

510(k) Number K072712

F1