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

K072711

OCT 9 2007

" 510(k) SUMMARY "

Submitter's Name: ***COMFORT ORTHOPEDIC CO., LTD.***
N0. 120, NAN SHIANG TSUEN, SHOEI SHANG SHIANG, CHIA-YI, 608, TAIWAN, ROC

Date summary prepared: September 21, 2007

Device Name:

Proprietary Name: COMFORT POWERED WHEELCHAIR, LY-EB206
Common or Usual Name: Powered Wheelchair
Classification Name: Powered Wheelchair, Class II, 21 CFR 890.3860

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 POWERED WHEELCHAIR, LY-EB206 is an indoor / outdoor Electric Wheelchair 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 Powered Wheelchair, LY-EB103 (**K030356**)

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Summary for substantial equivalence comparison:

We can know from the above table that the intended use between the two devices is the same. Mainframes of two devices are foldable. Mainframes materials of the two devices all meet the strength and fatigue tests and they are similar for the material aspects. The overall dimensions are similar. 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, weight limit, and warranty are all the same. They are substantially equivalent.

Especially the electronic systems between two devices are the same and all passed by the UL certificated, for instance the electronic controller, batteries, motor, and recharge. Thus the same safety level for the two devices is assured.

The major differences existing are the overall dimension and the sizes of tires 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 4.75 mph for the new device and 5.31 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.

Maximum range per charge is different, and new device is 23.8 miles and 20 miles for the predicate device. Certainly the real range depends on the practical environments, i.e., weight, surface, incline, and temperature. For the real life use, the two devices are substantially equivalent.

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 dimensions and material differences exist. We believe that FDA can decide the subject device and the predicate device are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Re: K072711
Trade/Device Name: Comfort Powered Wheelchair, LY-EB206
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: September 21, 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.

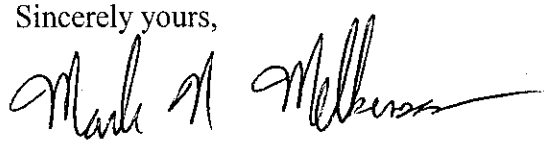
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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,



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): K

Device Name: *COMFORT POWERED WHEELCHAIR, LY-EB206*

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

510(k) Number 10/31/07 K072711