K092130

SEP 2 1 2009

510(k) Submission Summary – "We Go 250" Powered Wheelchair

In accordance with 21 CFR 807.92, the following information constitutes the summary of safety and effectiveness of the Rascal "We Go 250".

Submitter's Name: Electric Mobility (d.b.a. The Rascal Company)
591 Mantua Blvd., Sewell NJ 08080
FDA Registration Number: 3005191512
Owner/Operation Number: 2244608
Official Contact: Steve Beversluis – Director of QA/Regulatory

Date Summary Prepared: July 6, 2009

1. Device Identification:

Proprietary Name: Rascal "We Go 250"
Generic Name: Powered Wheelchair
Predicate Device: Merits Powered Wheelchair K011687
Classification of Predicate Device: Powered Wheelchair, Class II 21 CFR 890.3860
Product Code: ITI
Classification Name: Powered Wheelchair, Class II 21 CFR 890.3860

2. Intended Use:

The device is intended to provide mobility to persons restricted to a seated position or who are mobility impaired.

3. Device Description:

The Rascal "We Go 250" Powered Wheelchair is an indoor/outdoor use battery operated wheelchair. It has a frame with four (4) wheels, a seat, two (2) arm rests and a seat belt. The primary technology advantage of this device is that the movement of the wheelchair can be controlled by the rider or an attendant using hand controls located at the top of steering column to adjust the speed and direction of the wheelchair with occupant therein. These hand controls for the attendant are the same controls used for most electric scooters (Motorized Three Wheeled Vehicles – Regulation Number 890.3800). We currently market electric scooters with that same technology (510k K002616). The brake mechanism is activated or deactivated dependant upon the use of the hand controls located at the top of the steering column.

The base of the wheelchair is same base currently used on 510k approved device (K013788)

4. Predicate Device:

The Rascal Company believes that the Rascal "We Go 250" is substantially equivalent to the following predicate device:

Merits Health Products Company Ltd. K011687

5. Technological Characteristics:

This device has the same intended use as the legally marketed device(s), as shown in the substantial equivalence table, with technological characteristics that do not raise questions on the safety and effectiveness during use.

6. Performance Testing:

An extensive collection of tests has been conducted and successfully completed, including all testing in accordance with FDA Recognized Consensus Standards for Powered Wheelchairs. Product Code ITI, Regulation Number 890-3860. All testing indicates that the Rascal "We Go 250" meets its performance requirements.

7. Conclusion:

The Rascal "We Go 250" Powered Wheelchair has the same intended use and similar technological characteristics as the legally marketing device Merits Powered Wheelchair MP3 (P320). Moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any questions as to safety and effectiveness. Thus, the Rascal "We Go 250" is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 21 2009

Electric Mobility Corporation
% Mr. W. Stephen Beversluis
Director of Quality/Regulatory
1 Mobility Plaza
Sewell, New Jersey 08080

Re: K092130
Trade/Device Name: Rascal "We Go 250" Powered Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: July 6, 2009
Received: July 15, 2009

Dear Mr. Beversluis:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE STATEMENT

510k Number: _____

Device Name: Rascal "We Go 250" Powered Wheelchair

Indications for Use:

The Rascal "We Go 250" Powered Wheelchair is intended to provide mobility to persons restricted to a seated position or who are mobility impaired.

Prescription Use ____X_____ and/or Over-The Counter Use _____X_____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092130