510(k) Summary of Safety and Effectiveness

Manufacturer Name:	Rogue Wheels Inc.
Postal Address:	171 East Liberty Street, Unit #102 Toronto, Ontario Canada M6K 1W9
Phone Number:	416-535-2939
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Contact:	Jeff Adams
Title:	President
Date:	October 3, 2008

Device Proprietary Name:	Marvél Wheelchair
Device Common or Usual Name:	Mechanical Wheelchair
Classification Name:	Wheelchair Mechanical
Classification Code	IOR – Class I
Classification Panel	Physical Medicine
Regulation Number	890.3850

Predicate Device

Substantial equivalence is claimed to the following device as related to intended use and design characteristics:

- Stryker Sorano Wheelchair, K051369

Intended Use

The Marvél Wheelchair is a mechanical wheelchair intended to provide mobility to persons restricted to a seated position.

Description of the Device

The Marvél Wheelchair is a manually operated, user propelled mechanical wheelchair. It is intended to provide mobility to persons restricted to a seated position. It can be operated on most indoor and outdoor surfaces, with the exception of stairs.

The frame is constructed primarily of aluminium but with titanium elements in specific areas to reduce vibration and weight. Large rear wheels with handrims propel the chair and smaller front pivoting casters provide stability. The wheelchair is a lightweight manual chair designed for everyday use, both indoors and outdoors. The wheelchair is a rigid, non-folding type wheelchair.

The Marvél wheelchair consists of three major components or sections in addition to the large rear wheels: the caster wing assembly, the main frame assembly and the seating assembly.

The Marvél Wheelchair offers modularity and a number of adjustability features. The seat height, width, angle, rear seat-to-floor height, and front seat-to-floor height may be adjusted easily for the comfort of the user. Modularity allows replacement of worn components and allows the user to continually customize their own chair to ensure optimal functionality for their lifestyle.

Performance Data:

The Marvél Wheelchair will meet the applicable performance standards specified in Rehabilitation Engineering Society of North America (RESNA) Standard ANSI/RESNA WC/Vol. 1-1998 "Requirements and Test Methods for Wheelchairs".

Substantial Equivalence

The Marvél Wheelchair is similar to the Stryker Sorano Wheelchair based on the intended use, design, technology, material composition and performance.

Conclusion

The Marvél Wheelchair does not raise any new safety and efficacy concerns when compared to a similar legally marketed device. Therefore, the Marvél Wheelchair is substantially equivalent to the predicate device identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2008

Rogue Wheels Inc.
% CanReg Inc.
Kathryn Ronalds, RAC
Regulatory Affairs Manager, Devices
4 Innovation Drive
Dundas, Ontario
Canada L9H 7P3

Re: K082970
Trade/Device Name: Marvél Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair.
Regulatory Class: Class I
Product Code: IOR
Dated: October 3, 2008
Received: October 6, 2008

Dear Ms. Ronalds:

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

Indications for Use

510(k) Number:

Device Name: Marvél Wheelchair

Indication for Use: The Marvél Wheelchair is a mechanical wheelchair intended to provide mobility to persons restricted to a seated position.

Prescription Use _____ And/Or Over the Counter Use __X__
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation

Division Sign-Off
Office of Device Evaluation

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) K082970

510(k) Number K082970