

1030783

APR 04 2003

**510(k) Summary
Innovation In Motion
510(k) Premarket Notification
Frontier Power Wheelchair**

Applicant's Name, Address, Telephone, and Fax Numbers

Innovation In Motion
900 Growth Parkway
PO Box 507
Angola, IN 46703
Phone 260.668.5677 Fax: 260.668.8967

Preparer's Name, Address, Telephone, Fax Number, Contact Name, and Date Prepared

Innovation In Motion
900 Growth Parkway
PO Box 507
Angola, IN 46703
Phone 260.668.5677 Fax: 260.668.8967

Contact Person: Rick Michael
North America Sales Manager

Date Prepared: February 2003

Manufacturer's Name, Address, Telephone, and Fax Numbers

Magic International Pty. Ltd.
2 / 16 Viewtech Place
Rowville, Victoria 3178
Australia
Phone: 011.613.9755.8100 Fax: 011.613.9755.8111

Name of Device and Name/Address of Sponsor:

Frontier Power Wheelchair

Innovation In Motion
900 Growth Parkway
PO Box 507
Angola, IN 46703
Phone 260.668.5677 Fax: 260.668.8967

Common or Usual Name

Power Wheelchair

Classification Name

Wheelchair, Powered

Predicate Devices

The product that is substantially equivalent to the Frontier Power Wheelchair is Invacare's Xterra GT Power Wheelchair (K012909, October 24, 2001).

Intended Use

The intended use of the Frontier Power Wheelchair is to provide mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair.

Technological Characteristics and Substantial Equivalence**Device Description:**

The Frontier Power Wheelchair is a battery powered, electric motor driven device with the intended function of providing mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair. It is a mid wheel drive format wheelchair as it's basic configuration with direct drive motors and four swivel castors. The wheelchair frame is of a non-folding type with a mid mounted drive wheels on individual, front pivoting extension arms ending in front mounted swivel castors. The rear of the main frame ends with a lateral pivoting beam arm with swivel castors mounted on each side. This frame design allows for all 6 wheels to contact the ground over uneven terrain.

The frame consists of a combination of 2" diameter round steel tube, 1 1/4" diameter round steel tube and 1 1/4" square tube. The wheelchair consists of the following basic components: frame with articulated drive wheels and casters, seat, armrests, and footrests.

Substantial Equivalence:

Both of these products are battery powered wheelchairs with the same intended function and use—the provision of mobility to persons limited to a sitting position that have the capability of operating a powered wheelchair. Similarities include large mid-wheels with attached motor/gearbox drive mechanisms, smaller pivoting casters for turning, and joystick operated motor controllers to engage system motion and steer the wheelchair. They are all constructed from the same basic materials, have the same basic operational principles, and all use DC batteries as their source of power.

The Frontier Power Wheelchair is substantially equivalent to **Invacare's Xterra GT Power Wheelchair (ZX2) (K012909, October 24, 2001)**.

Performance Data:

As required by FDA's July 26, 1995 draft publication entitled "Guidance Document for the Preparation of Premarket Notification [510(k)] Application for Mechanical and Powered Wheelchairs, and Motorized Three--Wheeled Vehicles", the Frontier Power Wheelchair was tested in accordance with ISO/CD 7176-21 and ANSI/RESNA Vol.2 Section 21 Amendments for powered wheelchairs and motorized scooters. In all instances, the Frontier Power Wheelchair met the required performance criteria and functioned as intended.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 04 2003

Mr. Rick Michael
North America Sales Manager
Vestil Manufacturing Corporation
900 Growth Parkway
Angola, IN 46703

Re: K030783
Trade/Device Name: Frontier Power Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: March 25, 2003
Received: March 26, 2003

Dear Mr. Michael:

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.

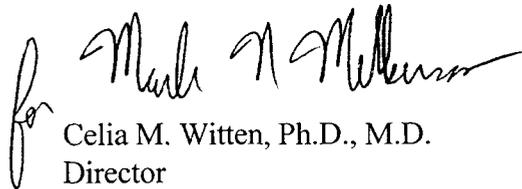
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the typed name.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): TBD

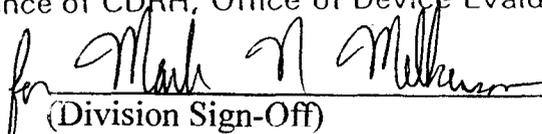
Device Name: Frontier Power Wheelchair

Indications For Use:

The intended use of the Frontier Power wheelchair is to provide mobility to persons limited to a sitting position, who have the capability of operating a power wheelchair

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

Concurrence of CDHR, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative
and Neurological Devices

510(k) Number K030783

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)