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510(k) SUMMARY

Nutron and Pronto Series Power Wheelchairs (M50, M51, M71, M91) with MKV-NX series of wheelchair controllers

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Invacare Corporation
One Invacare Way
PO Box 4028
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person: Rae Ann Farrow
Manager, Regulatory Compliance

Date Prepared: May 21, 2002

Name of Device and Name/Address of Sponsor

Nutron and Pronto Series Power Wheelchairs (M50, M51, M71, M91) with MKV-NX series of wheelchair controllers

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036-2028
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Common or Usual Name

Power Wheelchair

Classification Name

Wheelchair, Powered

Predicate Devices

The Invacare powered wheelchairs with the MK-NX controller are substantially equivalent to devices that are currently being legally marketed within the United States, including **Invacare Xterra GT power wheelchair (K012909, 10/24/2001)** and the **Invacare Pronto M71 power wheelchair (K012927).**

Intended Use

The intended function and use is to provide mobility to persons limited to a sitting position that have the capability of operating a powered wheelchair.

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Technological Characteristics and Substantial Equivalence

A. Device Description

The purpose of this pre-market notification is to request marketing clearance from FDA to change the controller of certain power wheelchairs models, manufactured by Invacare Corporation, which have already been granted marketing clearance by FDA under separate submissions

The controller change applies to the Invacare Pronto Powered Wheelchair Series (K012927, 9/19/2001), and the Nutron Powered Wheelchair Series (K900565, 2/15/1990). Each of these devices are battery powered, motorized mobility vehicles. Their intended function and use, which has not changed, is to provide mobility and transportation to physically challenged persons that may be restricted to a seated position.

The controller for the Nutron and Pronto Series of Wheelchairs is being modified from the Invacare MKIV-RII controller to the Invacare MKV-NX controller. The Invacare MKV-NX controller, which is the subject of this premarket notification, is an electronic, microcomputer based, motion control device designed for use with Invacare powered wheelchairs. The intended function of the controller is to activate and control powered wheelchair motions. Additionally, it provides a method of adjusting, selecting and programming certain powered wheelchair performance characteristics to better suit the specific control needs of the user.

Two versions of the controller will be available. These are the MKV-NX and the MKV-NX LP. The MKV_NX version has full programming capability, while the MKV-NX LP version has limited programming capability. Programming capability for the LP version is limited to forward speed, turning speed, and reverse speed only. Otherwise the controllers are identical.

The Invacare MKV-NX and MKV-NX LP controllers are programmed using the Invacare MIV remote programmer, previously cleared with the Model MCC-MKIV Micro Computer Control (K940972, 6/2/1994). The controller software and electronics will not allow wheelchair operation during programming.

B. Substantial Equivalence

The Invacare powered wheelchairs with the MK-NX controller are substantially equivalent to devices that are currently being legally marketed within the United States, including **Invacare Xterra GT power wheelchair (K012909, 10/24/2001)** and the **Invacare Pronto M71 power wheelchair (K012927).**

PERFORMANCE DATA

The Invacare Elevating Seat meets the applicable requirements specified in the Rehabilitation Engineering Society of North America (RESNA) Standard ANSI/RESNA WC/14 (1991) and ISO Standard ISO 7176: 1993(E), "ISO Standard, Wheelchairs - Requirements and Test Methods for the Power and Control Systems of Electric Wheelchairs."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 8 2002

Ms. Rae Ann Farrow
Manager, Regulatory Compliance
Invacare Corporation
One Invacare Way
PO Box 4028
Elyria, OH 44036-2125

Re: K021680
Trade Name: Invacare Powered Wheelchairs, Models M50, M51, M71 and M91
Regulatory Number: 890.3860
Regulatory Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: May 21, 2002
Received: May 22, 2002

Dear Ms. Farrow:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N Melkerson

Celia 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: *Nutron and Pronto Series Power Wheelchairs (M50, M51, M71, M91) with MKV-NX series wheelchair controllers*

Indications For Use:
The intended function and use is to provide mobility to persons limited to a sitting position that have capability of operating a powered wheelchair.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109)

Mark N Milkerson
for (Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021680

(Optional Format 1-2-96)