AUG 12

K992052

510(k) SUMMARY
INVACARE CORPORATION'S
510(k) PREMARKET NOTIFICATION
MODELS LYNX AND PANTHER MOTORIZED SCOOTERS

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

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

Contact Person: Edward A. Kroll
Director, TQM and Regulatory Affairs
Date Prepared: June 11, 1999

Name of Device and Name/Address of Sponsor: Models Lynx and Panther Motorized Scooters.

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 366-9724

Common or Usual Name
Scooter

Classification Name
Motorized Three Wheel Vehicle

Predicate Devices

Products which are substantially equivalent to the Model Lynx and Panther Scooters are; Invacare Action Cat three wheeled scooter (K962583, 12/18/96) the Mega Motions Inc. Mega 4 scooter (K982144, 4/14/99), and the Pride Mobility Inc. Celebrity (K944939, 11/7/94).

Intended Use

The intended use of the Lynx and Panther scooters is to is provide mobility to persons limited to a seated position.

There are two models of Scooters in the Panther series. These are the **Panther LX - 4** and the **Panther MX - 4.** A brief description of each is as follows.

Panther LX - 4

The **Panther LX - 4** scooter is basically the same as the **Lynx LX - 3** scooter except that the Panther LX -4 is a **four wheeled vehicle** whereas the Lynx LX - 3 is a **three wheeled** vehicle. It includes the same transaxle motor drive system, braking system, adjustable seat, upholstery, covers, tiller handle and throttle control as the Lynx LX - 3. Additionally, it incorporates the same Penny & Giles "Solo 60" motor controller and the Lynx version and it has an on board battery charger.

Because the Panther LX - 4 is a four wheel vehicle, the welded steel frame is slightly different than the Lynx version. While the rear section of the frame is basically the same, the front portion differs such that it can accept two front wheels as opposed to one wheel on the Lynx. With these exceptions, the Panther LX - 4 is basically the same as the Lynx LX - 3.

Panther MX - 4

The Panther MX - 4 is the largest scooter in the Invacare Lynx/Panther. Like the Panther LX -4 , the Panther MX - 4 is a four wheeled vehicle. It has the same intended function and use as the others, and consists of the same technology and construction. Like the others, it basically consists of a welded steel frame, transaxle drive mechanism, braking system and seat assembly. Also, it includes a tiller handle for steering, and a throttle control to engage and disengage scooter motion in both the forward and reverse directions.

The Panther MX - 4 differs from the others in the Lynx/Panther series in that it is designed as a heavy duty, more durable scooter with a recommended weight limitation of 400 lbs. maximum. It is larger and heavier than the others, and includes more options and features. As such the frame, transaxle drive and braking system are different from the others and , the Panther MX - 4 scooter is powered using a Penny & Giles model "Solo 110" motor controller.

Substantial Equivalence

Products which are substantially equivalent to the Invacare Action Cat three wheeled scooter (K962583, 12/18/96) the Mega Motions Inc. Mega 4 scooter (K982144, 4/14/99), and the Pride Mobility Inc. Celebrity (K944939, 11/7/94). Each of these products are motorized, three and four wheeled scooters with the same intended function and use of providing mobility to persons limited to a seated position. All are all constructed from the same basic materials and components, all have the same basic operational principles and all use DC batteries as their source of power. Drive mechanisms and braking systems are also similar as are performance specifications for speed, acceleration, deceleration, turning radius and braking.

Technological Characteristics and Substantial Equivalence

Device Description

The Invacare Models Lynx and Panther scooters are motor driven indoor and outdoor transportation vehicles. The Lynx series of scooters are three-wheeled vehicles while the Panther Series of scooters are four-wheeled vehicles.

All of the scooters products are basic conventional rear wheel drive, rigid frame vehicles that are battery powered, and include various options and accessories depending upon user needs and preferences. They all consist primarily of a welded steel frame, transaxle motor drive system, braking system, electronic motor controller and an adjustable seat. Like most scooters, they include a tiller handle for steering, and a throttle control to engage and disengage scooter motion in both the forward and reverse directions. They are all powered by two (2) 12 volt DC batteries, and they all include a variety of options and accessories in order to meet the needs and preferences of various users.

LYNX SERIES SCOOTERS

Lynx SX-3 and SX-3P

As stated above the Lynx series of scooters are three-wheeled vehicles as opposed to the Panther series which are four wheeled. The Lynx series includes three different models These are the **Lynx SX-3, Lynx SX-3P and the Lynx LX-3**. The models are basically same with a few subtle differences.

The SX 3 and SX 3P differ only in that the SX - 3 includes an "on board" battery charger, which is fixed to the scooter, while the SX - 3P requires a remote and separate battery charger. There are also certain cosmetic differences such as shroud color availability, bumper trim, wood grain decorative decals and the like, which are included on the SX-3 version, but, not on the SX 3P version.

Lynx LX-3

The Lynx LX-3 scooter is similar to the Lynx SX-3 and SX-3P, but, is slightly larger. Like the SX-3 and SX3P, it is a three-wheel vehicle. However, it is designed to be a more heavy duty version scooter, with higher maximum weight capacity than the others in the Lynx series. Where the SX versions are rated for a maximum user weight of 200 lbs., the LX-3 version is rated for a maximum user weight of 250lbs.

PANTHER SERIES

The Invacare Models Panther scooters are motor driven indoor and outdoor **four wheeled** transportation vehicles. Like the Lynx series of scooters these products are basic conventional rear wheel drive, rigid frame vehicles that are battery powered, and include various options and accessories depending upon user needs and preferences. They also consist primarily of a welded steel frame, transaxle motor drive system, braking system, electronic motor controller and an adjustable seat. They include a tiller handle for steering, and a throttle control to engage and disengage scooter motion in both the forward and reverse directions, and are powered by two (2) 12 volt DC batteries.

PERFORMANCE DATA

The Invacare Models Lynx and Panther scooters meet 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

AUG 12 1999

Mr. Edward A Kroll
Director, TQM and Regulatory Affairs
Invacare® Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036-2125

Re: K992052
Trade Name: Models "Lynx" and "Panther" motorized scooters
Regulatory Class: II
Product Code: INI
Dated: June 17, 1999
Received: June 18, 1999

Dear Mr. Kroll:

We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General Regulation (21 CFR Part 820), and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known): *TBD*

Device Name: *Invacare Models Lynx and Panther Motorized Scooters*

Indications For Use: *To provide mobility to persons limited to a seated position..*

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992052