MAR 2 0 2003

K030814

510(k) SUMMARY
INVACARE CORPORATION'S
510(k) PREMARKET NOTIFICATION
ADVENTURE 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: Rae Ann Farrow
Manager, Regulatory Compliance

Date Prepared: March 13, 2003

Name of Device and Name/Address of Sponsor:

Name of Device: Invacare Adventure Series 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
The Adventure Scooters are substantially equivalent to the Lynx scooters (K010135, 2/16/2001).

Intended Use
The intended use of the Adventure scooters is to provide mobility to persons limited to a seated position.

Technological Characteristics and Substantial Equivalence

Device Description

The Invacare Adventure Series of Scooters are motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to persons limited to a seated position.

The scooters are basic conventional rear wheel drive, rigid frame vehicles that are battery powered. Various options and accessories are available depending upon user needs and preferences. They consist primarily of a welded steel frame, transaxle motor drive system, braking system, electronic motor controller and an adjustable seat. They also include a tiller handle for steering and a throttle control to engage and disengage the scooter motion in both the forward and reverse directions. The scooters can also be disassembled for ease of transport, are powered by two (2) 12 volt DC batteries, and utilize an on-board charger.

The scooters have a status indicator located on the face of the control panel that provides diagnostic information. The status LED will flash a certain number of times, separated by a pause when a fault is detected in the controller or in the wiring. This feature is for diagnostic information only and does not control the operation of the scooter.

The Adventure SX-3 is a compact version of the scooter with a 250 lb. weight capacity while the Adventure LX-3 scooter is a mid-size version of the scooter with a 350 lb. weight capacity.

Substantial Equivalence

Products, which are substantially equivalent to the Invacare Adventure scooters, include the Invacare Lynx SX-3, Lynx LX-3, and Lynx LX-3^{Plus} scooters, which were granted clearance by FDA on February 16, 2001 on 510(k) accession number K010135. Each of these products are motorized, 3-wheel scooters with the same intended function and use of providing mobility to persons limited to a seated position.

While there are minor differences in performance specifications of the scooters, these differences do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness. Therefore, Invacare believes that the Adventure series of scooters are substantially equivalent to legally marketed devices currently in commercial distribution.

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. The upholstery materials meet California 116 and 117 specifications for fire retardancy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2003

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

Re: K030814
Trade/Device Name: Invacare Adventure Series Scooters
Regulation Number: 890.38002
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: March 13, 2003
Received: March 14, 2003

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.

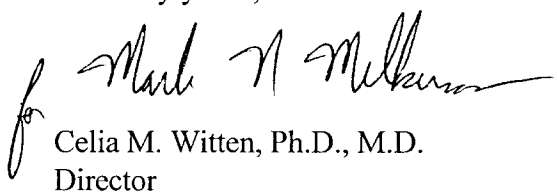
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), 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,



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: Invacare Adventure Series Scooters

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

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

510(k) Number K030814

(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)

(Optional Format 1-2-96)