510(k) SUMMARY

Invacare Corporation's Action Cat Scooter with DS60 Controller

K962583

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

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Name of Device and Name/Address of Sponsor

Action Cat Scooter with DS60 Controller

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Common or Usual Name

Powered scooter

Classification Name

Motorized three-wheeled vehicle

Predicate Devices

The Action Cat Scooter with DS60 Controller ("Action Cat Scooter with DS60 Controller ") is substantially equivalent to Invacare Corporation's Cat Scooter (K941966).

Intended Use

The Action Cat Scooter with DS60 Controller is intended to be used to provide mobility to persons restricted to a seated position.

Technological Characteristics and Substantial Equivalence

A. Device Description

As indicated above, the Action Cat Scooter with DS60 Controller is intended for use to provide mobility to persons restricted to a seated position. The scooter has a total weight of 160 pounds (including batteries), and its overall width, track, and wheelbase are 24", 34", and 46", respectively. All upholstery on the device is flame rated to FMVSS302 and CMVSS302. The maximum grade is 9 degrees with a 300 pound load, and the leakage current is less than 100 amperes. The maximum load is 300 pounds, and the maximum speed for the scooter is 5 (±1) mph. The scooter does not have separate "slow," "normal," and "fast" speed control modes; instead, the speed of the vehicle simply is determined on a continuous range by how far the user pushes the speed control bar/tiller.

The braking system for the scooter is electromechanical. Activation of the throttle speed control (either forward or reverse), causes the engagement of an electromagnet which overcomes spring pressure and releases the brake. Releasing the throttle causes the motor control board to induce dynamic braking and reduce speed. Once motor revolution reaches zero, the electromagnet will release, allowing the spring pressure to apply the brake. As an additional feature, the scooter will not operate if the brake is disconnected. The brake is designed to hold a 400 pound load on a 15 degree incline. On level ground with dry conditions and a 300 pound load, braking time from a top speed of 6 mph to zero is 1 second and requires a distance of 5 feet.

The Action Cat Scooter with DS60 Controller uses two 12 volt gel cell batteries. The scooter's range on a standard charge varies according to temperature and battery condition, but the average range is approximately 25 miles. The front approach angle for the Action Cat Scooter with DS60 Controller is 71 degrees, and the rear departure angle is 13 degrees. At the scooter's center, the ground clearance from the chassis is 3.0". Likewise, the maximum curb clearance is 3.0". The breakover angle is 10 degrees, and the minimum radius at which the Action Cat Scooter with DS60 Controller will not tip (at maximum speed) is 6 feet.

The controller for the scooter is a Model DS60 system for DC motor control applications. The DS60 Controller is designed to operate with a nominal 24 volt battery input and to yield a maximum output current of 60 amperes. It also is designed to control a single conventional permanent magnet DC motor with a solenoid-controlled motor brake. The controller incorporates motor load compensation which provides precise motor control over a wide range of driving conditions, thereby maintaining the selected speed of the scooter at a constant level,

regardless of the surface type or grade on which the vehicle is driven. This feature ensures less roll-back when stopping the Action Cat Scooter on a slope. The correct level of load compensation depends on the type of motor used and the length of the wiring, and is easily set using the separate handheld DS Programmer.

The programmable features of the DS60 Controller include forward/reverse acceleration, forward/reverse deceleration, motor resistance, etc. It should be noted, however, that although the DS60 Controller for the modified Cat Scooter is programmable, all parameters for the controller will be set only by the factory (i.e., Invacare) prior to sale, and no modifications will be made by either the retailer or the user of the scooter. The DS100 Programmer will not be available for purchase.

The DS60 Controller is a single printed circuit board fixed to an aluminum base. A plastic vacuum-molded case protects the electronics of the DS60 Controller. The DS60 Controller also is protected against accidental reverse battery connection.

Several accessories are available through Invacare for the modified Action Cat Scooter. These options are: a basket, antitipper components, a flat-free insert, an extended throttle lever, a safety flag, a crutch/cane carrier, and a spare key set. The Action Cat Scooter with DS60 Controller also is available in a compact style which measures 43½ inches in length (versus 50" for the regular size scooter).

B. Substantial Equivalence

The predicate Cat Scooter also provides essentially the same specifications, functions, characteristics, and accessories as described above for the Action Cat Scooter with DS60 Controller. The predicate motorized three-wheeled vehicle is nearly identical to the Action Cat Scooter with DS60 Controller and has the same intended use. The following specifications for the predicate Cat Scooter are the same as those for the Action Cat Scooter with DS60 Controller:

- Total weight;
- Track;
- Wheelbase;
- Maximum speed;
- Motor/gears;
- Maximum grade;
- Maximum load;
- Leakage current;
- Braking system;
- Batteries;
- Front approach angle;
- Rear departure angle;
- Ground clearance;
- Breakover angle; and

•Minimum non-tipping radius (at maximum speed).

Although there are some differences between the Action Cat Scooter with DS60 Controller and its predicate, these differences are minor and raise no new questions of safety and effectiveness. The only significant difference between the two models is that the newer version has a digital controller while the predicate is equipped with an analog controller. Thus, unlike the digital controller for the modified Action Cat Scooter with DS60 Controller, the the controller for the predicate device was not programmable and did not utilize software. But even this disparity is small, as the DS60 only will be programmable by the factory (i.e., neither the dealers nor the users will be able to change the factory presets). Furthermore, both controllers have essentially identical input/output parameters and safety features.

Other more minor differences in the Action Cat Scooter with DS60 Controller versus the original Cat Scooter include the addition of a standard on-board charger, an increase in the labeled weight limit from 250 pounds to 300 pounds, the option of a compact model, and the addition of a height-adjustable seat. Thus, the differences in technological characteristics between the Action Cat Scooter with DS60 Controller and its predicate device are minor and do not present any new issues of safety or effectiveness.

Performance Data

As required by FDA's July 26, 1995 draft publication entitled "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles", the Action Cat Scooter with DS60 Controller was tested in accordance with ISO EMC Draft Standard 7176-14 (Titled "Draft ISO EMC Group Proposal: Electromagnetic Compatibiliity Addition" And Dated April 3, 1995) for powered wheelchairs and motorized scooters. In all instances, the Action Cat Scooter with DS60 Controller met the required performance criteria and functioned as intended. The Action Cat Scooter with DS60 Controller also passed a number of performance tests performed voluntarily by Invacare.