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510(k) SUMMARY

Invacare Corporation's Model Dx Micro Computer Controls for Power Wheelchairs

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

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Date Prepared: January 10, 1997

Name of Device and Name/Address of Sponsor

Model Dx Micro-Computer Control for Power Wheelchairs

Invacare Corporation
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Phone: (216) 329-6000
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Common or Usual Name

Power Wheelchair

Classification Name

Wheelchair, Powered - 89ITI

Predicate Devices

The Model Dx Micro-Computer Controls are substantially equivalent to Invacare Corporations' Model MCC MKIV Micro Computer Controls (K940972 June 2, 1994), and Invacare's Model INT DL40i Wheelchair control (K950274, August 7, 1995).

Intended Use

The intended use of the Model DX Micro-Computer Control is to activate and control power wheelchair motion.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Model Dx Controller is a series of electronic, microcomputer based, motion control devices for use with power wheelchairs. Their intended function and use is to activate and control power wheelchair motion. Additionally, they provide a method of adjusting, selecting and programming the type of power wheelchair performance characteristics which best suit the specific control needs of the wheelchair user.

The Dx product line includes a motor controller power module with microprocessor, and a variety of joystick options and accessories which are used to perform various functions. The power module, which contains the system microprocessor, is housed in a pressure die cast aluminum enclosure. The power module stores preprogrammed operating functions, processes user inputs and issues commands to the wheelchair motors. The joystick options are used to engage wheelchair motion and to steer the chair. The options and accessories are used to program the wheelchair performance parameters and to perform additional functions as needed by the wheelchair user.

B. Substantial Equivalence

Products which are substantially equivalent to the Dx Controls are; Invacare's Model MCC-MKIV Micro Computer Controls (K940972) and Invacare's (Dynamic Controls) Model INT DL 40i Micro Computer Controls for Power Wheelchairs (K950724).

Each of these products are electronic microcomputer based motor control devices for use with power wheelchairs with the same intended function and use which is to activate and control power wheelchair motion. Additionally, all provide the means for selecting, adjusting and programming the type of wheelchair operation parameters and performance characteristics which best suit the particular needs of the wheelchair user. Finally, all of these devices have been granted marketing clearance by FDA under prior submissions.

None of the differences between the Dx Controller and its' predicate devices alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness.

PERFORMANCE DATA

The Dx Controller has been tested for compliance with ISO 7176:1993(E) entitled ISO Standard, Wheelchairs - Requirements and Test Methods for the Power and Control Systems of Electric Wheelchairs." Results indicate that the Dx Controller meets the requirements of this standard.