

CONFIDENTIAL

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Appendix F

**Summary of Safety and Effectiveness for
Quickie Powered Wheelchair with Penny and Giles Controller**

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Name(s) of the device

P100 series

Identification of predicate device(s)

P100, P110, P190, P500, P500, P200, P210, P320, P300
Everest and Jennings Lancer 2000, Sabre, Sabre ES
Prode Health Care Inc. Jazzy

Description of the device

Quickie powered wheelchairs consist of typical features found on any wheelchair, such as push handles, adjustable armrests, backrest, seat frame and cushion, footrests, and casters. Because these are motorized wheelchairs, they also consist of joy stick controller, motors, brakes, batteries and drive wheels.

Intended Use

Quickie Powered Wheelchairs empower physically challenged persons by providing a means of mobility.

Comparison of device characteristics to predicate

This 510(k) is for a change in the wheel chair controller. The power wheelchair specifications have not been changed due to this modification. The New controller subject to this 510(k) is the P&G Controller that has been available on other lines of power wheelchairs, including Pride Health Care's Jazzy, Everst and Jennings Lancer 2000 and Sabre, and Hoveround Personal Mobility Vehicles. Everest and Jennings recently made the same switch in controllers as Quickie; replacing the Dynamics Controller with a P&G 8 controller.

The P&G controller is based on Hitachi's H8/532 microprocessor while Dynamics is based on Motorola's 68HC705C8. The power wheelchair specifications have not been changed due to this modification.

Non clinical testing

Testing of all programmable parameters has been performed. These parameters include the following: maximum and minimum forward and reverse speeds, maximum and minimum turn speeds, maximum and minimum acceleration and deceleration, and maximum and minimum turn acceleration and deceleration. Comparative testing regarding speed, acceleration, brake distance demonstrate that the wheelchair performs as the predicate device with the Dynamics controller. Results demonstrate the wheelchairs perform according to specification. Electromagnetic compatibility testing was also performed on Quickie Power Wheelchairs, and results demonstrate that the wheelchairs pass the 20 V/m EMI test. Software validation information includes the software requirements, design, development and verification and validation of the controller as well as a hazards analysis and mitigation associated with the safety of the controller.

510(k) Number K963382

Not Known at the writing of this summary.

Conclusion

The Quickie Power Wheelchair is Substantially Equivalent to the previous versions of the Quickie Wheelchairs which utilize the Dynamics controller as well as other power wheelchair models which already incorporate the P&G 8 controller.