



HEALTHCARE SOLUTIONS, INC.

SEP 20 1995

**510(K) SUMMARY**  
**Powered Wheelchair**

November 29, 1995

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: \_\_\_\_\_

K955548

- Name of Device: **Wheelchair, Powered**
- Proprietary Name: CHIPS Powered Wheelchair
- Common Name : Powered Wheelchair
- Classification Name: Wheelchair, Powered
  
- Legally marketed device to which our company is claiming equivalence: Invacare Corp., trade name, Action, located at 899 Cleveland Street, Elyria, Ohio 44035, Sunrise Medical, trade name, Quickie, located at 2842 Business Park Ave., Fresno, CA 93727-1328, and 21st Century Scientific Inc., trade name, Boulder, located at 4915 Industrial Way, Coeur d'Alene, ID 83814.
  
- Description of Device: Powered Wheelchair. See attached letter
  
- Intended Use of Device: See attached description letter.
  
- Summary of technological characteristics of our device compared to the predicate device: Refer to Section 4 - Technical Specifications and Test Reports.
  
- Brief description of the nonclinical tests and how their results support a determination of substantial equivalence: Refer to, Section 4 - Technical Specifications and Test Reports.

Very truly yours,

Fred DiVito  
President



HEALTHCARE SOLUTIONS, INC.

**CHIPS POWER WHEELCHAIR  
DESCRIPTIVE INFORMATION**

**510(K) Pre Market Notification**

The specific intended use of the power wheelchair, which is the subject device, is identical to pre-existing or predicate devices.

I.H.S. CHIPS POWER CHAIR helps promote mobility, both indoors and outdoors, for the intended user commonly lacking full use of lower extremities. This limited use could be of short or long duration and caused by numerous medical conditions, ranging from spinal cord injuries to temporary broken bones in a lower extremity.

Our subject device provides mobility by incorporating a joy stick type controller which sends power to electric gear motors, which in turn are directly driving two rear wheels which propel the device.

This is very typical and common to predicate devices like those manufactured by Sunrise Medical, 2842 Business Park Avenue, Fresno, CA 93727 and Invacare, 899 Cleveland Street, Elyria, OH 44036. (Refer to Section 3 for details).

The controller on the subject device, similar to predicate devices, incorporates safety features such as, speed control, sensitivity control, battery life indicator and power on and off indicator light.

The above controller features are typically customized by the rehabilitation dealer, who has been instructed in the use and function of the product and who in turn instructs the end user in the use and function of the power chair. (Refer to Section 4 for details).

The main product components include a steel tubular welded frame which supports a sitting surface. (Refer to Section 4 for details).

Both the seat and the back support are made of a durable nylon material. In addition, the frame incorporates adjustable and removable armrests, providing support for the user, and is removable to facilitate transfer into and out of the wheelchair.

Both leg rests and foot rests are designed to be fully adjustable to accommodate a variety of anatomical differences.

All leg rests and foot rests assembly are designed to swing away to facilitate entry and exit to the power chair and are removable to facilitate transportation of the device.

All of the above described features are typical and common in predicate devices.



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CHIPS POWER WHEELCHAIR  
(cont.)

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Power is supplied to the device by incorporating two 12 volt wet or gel cell batteries providing a 24 volt system. This in turn supplies power to two rear mounted direct drive motors, both incorporating electromechanical automatic brakes. The motors in turn provide power to a sealed gear box which transfers power to the rear wheels.

The fully programmable control system provides reliable, precise control and conforms to the latest International Standards. It has plenty of drive to cope with curbs or hill climbing by continually monitoring motor voltage and current. It readily maintains constant speed over demanding uneven terrain and prevents unwanted rolling on slopes. It handles currents from 20 Amps to 70 Amps per channel, is fully programmable, incorporates true charge battery level indicator, has user speed and response controls, and a horn to alert others. (Refer to Sections 4 and 5 for details).

It incorporates sophisticated diagnostics to facilitate repair and provides speed stability on slopes for safety.

It incorporates hand tremor dampening for users who have poor motor control.

It has been manufactured to meet or exceed ISO 9001 and design to ISO 7176/14 and has been approved by International Regulations known as TUV and has surpassed Swedish Handicap Institute Approval. (All Test Criteria - Please Refer to Sections 4 and 5).

Fred DiVito  
November 29, 1995