AUG 25 1997

510(k) SUMMARY

K97247

Dynamic Systems, Inc.'s PHC-2

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

Dynamic Systems, Inc.
5002 North Royal Atlanta Drive, Suite P
Tucker, GA 30084-3050
Phone: (770) 939-1122
Facsimile: (770) 850-9875

Contact Person: David Court

Date Prepared: June 3, 1997

Name of Device and Name/Address of Sponsor

Dynamic Systems, Inc.
5002 North Royal Atlanta Drive, Suite P
Tucker, GA 30084-3050
Phone: (770) 939-1122
Facsimile: (770) 850-9875

Common or Usual Name

Peachtree Proportional Head Control Unit (PHC-2)

Classification Name

Power Wheelchair Control Unit

Predicate Devices

The PHC-2 ("PHC-2 ") is substantially equivalent to Adaptive Switch Laboratories. Inc.'s ASL Head Array, Invacare's Sip & Puff Head Array, Invacare's Remote Joystick, and Invacares R.I.M. control.

Intended Use

The PHC-2 is intended to provide mobility control to persons restricted to a seated position while operating a power-drive wheelchair.

Technological Characteristics and Substantial Equivalence

A. Device Description

The PHC-2 consists of a headrest pad containing a control unit which provides invisible contact between the user and the wheelchair. The control unit is a remote, electronic, two dimensional head position sensing device that utilizes a low level, high frequency electrical field to provide contact between the user and the wheelchair.

The PHC-2 control unit does not require physical attachments to the user. The user simply tilts his or her head to provide control commands to the wheelchair. The PHC-2 has two operational modes: control and drive, the user enters the various modes and functions by gently tapping the head rest a designated number of times. On power up, the unit is always in control mode which includes the following functions: stop, recline, ECU, and drive. The stop function results in no activity, recline allows the user to recline the back of the wheelchair with head motions, and the ECU function controls an environmental control unit, if available. The second level is drive mode which includes: stop, reverse, forward low, and forward high. Within the drive modes the user can accelerate, brake, spin, and turn by utilizing non-contact head movements.

B. Substantial Equivalence

The PHC-2 has the same intended use, similar principles of operation, and similar technological characteristics as the previously cleared predicate devices. Although there are minor differences in the characteristics of the PHC-2 and its predicate devices, those differences do not raise new questions of safety or efficacy.

Although there are some differences between the PHC-2 and its predicates, these differences are minor and raise no new questions of safety and effectiveness. The only significant differences between the named predicate devices and the PHC-2 are in the method employed to acquire user control input. The PHC-2 utilizes a remote, electronic, fully proportional, two dimensional head position sensing device to generate wheelchair control commands whereas the predicate devices either use

a joystick requiring physical contact or a nonproportional switch control mechanism to generate the commands.

Substantial Equivalence Table Comparing Dynamic Systems, Inc.'s PHC-2 with Predicate Devices

	PHC-2	ASL Head Array	SIP & PUFF	FLIGHT LINK JOYSTICK	R.I.M.
Intended Use	Movement Commanded Driving Control for Operating a Variety of Power Wheelchairs	Same	Same	Same	Same
Operating Principle	Capacitance Sensing	Fiberoptic Sensing	Air Pressure Sensing	Mechanical	Mechanical
Non-contact control	Yes	Yes	No	No	No
Device interface	Wheelchair Joystick Input Port	Same	Same	Same	Same
Proportional control	Yes	No	No	Yes	Yes
Movement control	Head	Head	Head	Hand	Head
Functions	Stop - Forward- Reverse - Turn - Spin -	Same	Same	Same	Same
Physical Characteristic	Headrest	Headrest	Headrest with Sip & Puff Pipe	Joystick	Headrest with Joystick

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David R. Court
Dynamic Systems, Inc.
5002 North Royal Atlanta Drive
Suite P
Tucker, Georgia 30084

AUG 25 1997

Re: K972147
Peachtree Proportional Head Control Unit (PHC-2)
Regulatory Class: II
Product Code: ITI
Dated: June 3, 1997
Received: June 9, 1997

Dear Mr. Court:

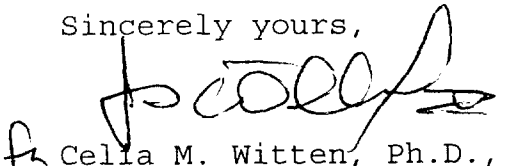
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K972147

Device Name: Peachtree Proportional Head Control (UNIT PHC-2)

Indications for Use: The Peachtree Proportional Head Control Unit is non-contact, fully proportional, head movement commanded driving control intended to provide mobility control to persons restricted to a seated position while operating a variety of available power-drive wheelchairs.

PLEASE DO NOT WRITE BELOW THIS LINE
(CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the-Counter Use X
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972147