

SEP 24 1999

K991090

510(k) SUMMARY

Dynamic Systems, Inc.'s
PHC-3

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

Dynamic Systems, Inc.
5002 North Royal Atlanta Drive, Suite P
Tucker, GA 30084
Phone: 770 939-1122
Facsimile: 770 939-7722

Contact Person: David R. Court

Date Prepared: September 15, 1998

Name of Device and Name/Address of Sponsor

Dynamic Systems, Inc.
5002 North Royal Atlanta Drive, Suite P
Tucker, GA 30084
Phone: 770 939-1122
Facsimile: 770 939-7722

Common or Usual Name

Peachtree Proportional Head Control Unit (PHC-3)

Classification

Power Wheelchair Control Unit

Predicate Devices

The PHC-3 is substantially equivalent to other legally marketed driver control systems for powered wheelchairs such as Dynamic Systems Inc.'s Peachtree Head Control PHC-2 (K972147), Adaptive Switch Lab's ASL Model #104 (K914737); Invacare's model MCC-MKIV Micro (Sip & Puff and R.I.M.) (K940972); and Invacare's Model #1555 Remote Joystick (K880364).



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K991090
Trade Name: Peachtree Head Control (PHC-3)
Regulatory Class: II
Product Code: ITI
Dated: July 6, 1999
Received: July 6, 1999

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.

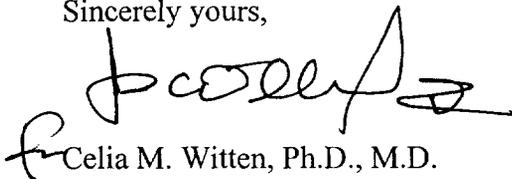
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Mr. David R. Court

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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and a long, sweeping tail.

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

510(k) Number (if known): K991090

Device Name: Peachtree Head Control (PHC-3)

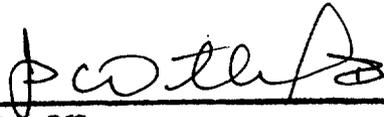
Indications For Use:

Indications for Use: The Peachtree Proportional Head Control model PHC-3 is intended to offer persons restricted to a seated position the ability to operate a powered wheelchair by three different methods. The first is a non-contact, fully proportional head movement commanded driving control. The next is controlled by a series of blowing and inhaling into a straw. This allows for four way directional control of the wheelchair. The last driving method uses a combination of the two previous drive controls. The user would tilt their head laterally to move the wheelchair left or right and blow or inhale into the straw to control forward/reverse direction/speed.

At current the PHC-3 has only been made to be compatible with Invacare's MKIV series of electronics and Dynamic Controls DX series of electronics.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K991090

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)