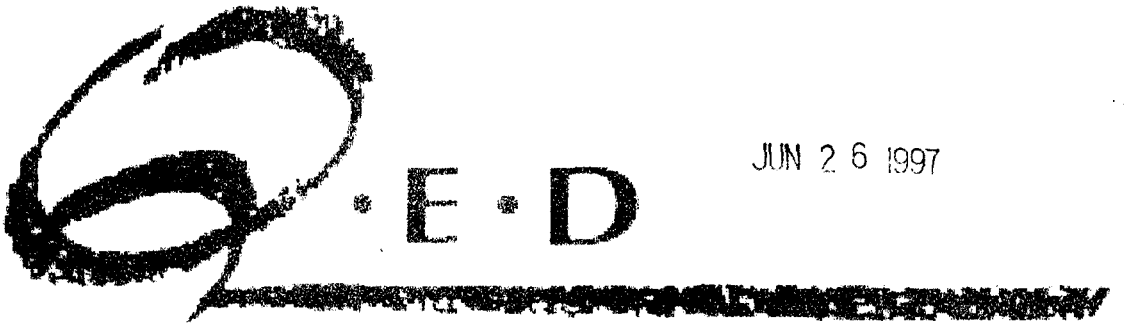
K970543



JUN 2 6 1997

Quest Enabling Designs Ltd
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242 Gosport Road
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PO16 0SS

Tel: +44 (0)1329 828444
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Pre-market Notification Summary

New Device

Trade Name:	Quest Enabling Designs Bobcat DX, powered wheelchair.
Common Name:	Powered wheelchair, with adjustable elevator.
Classification Name:	Physical Medicine, powered wheelchair.

Predicate Legally Marketed Device (claiming equivalence to)

510(k) Number:	K942508.
Trade Name:	Permobil Chairman ROBO, powered wheelchair.
Common Name:	Powered wheelchair, with adjustable elevator.
Classification:	Physical Medicine.
Product Code:	INI.

Description of New Device

Bobcat DX is highly manoeuvrable, electrically powered wheelchair. The unit consists of a front wheel drive chassis, enclosed in an attractive colourful fibreglass body, that is powered by a Control Dynamics DX microprocessor control unit. This control unit is controlled by a QED designed joystick, which has very sensitive buttons with good tactile feedback. The Bobcat DX comes complete with an elevating seat that allows the child independently to lower themselves to the floor, or to raise themselves to table height. There are many seating options available and we also supply a standing frame.

Intended Use of New Device

The highly manoeuvrable Bobcat DX enables children to determine their own activities without asking or waiting for assistance. Simultaneous development, emotional and physical, with their able bodied peer group removes the inevitable frustration which would otherwise set in.

Dynamic DX control system allows a high level of control and manoeuvrability, allowing use within the home or school environment, indoors and outdoors. Elevator allows the user to adjust both sitting and standing heights enabling greater participation in activities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Naheed Akhtar
Quest Enabling Designs Limited
Ability House, 242 Gosport Road
Fareham, Hampshire PO16 OSS

JUN 26 1997

Re: K970543
Trade Name: Quest Enabling Designs Bobcat DX
Regulatory Class: II
Product Code: IPL
Dated: April 7, 1997
Received: April 14, 1997

Dear Mr. Akhtar:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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,

Mark N Melkerson

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

Statements for Indications of Use.

Bobcat DX is highly manoeuvrable, electrically powered wheelchair. The unit consists of a front wheel drive chassis, enclosed in an attractive colourful fibreglass body, that is powered by a Control Dynamics DX microprocessor control unit. This control unit is controlled by a QED designed joystick, which has very sensitive buttons with good tactile feedback. The Bobcat DX comes complete with an elevating seat that allows the child independently to lower themselves to the floor, or to raise themselves to table height. There are many seating options available and we also supply a standing frame.

The child can easily adjust both sitting and standing heights, enabling participation at a table or bar for meals. Exclusion from normal eating areas and the necessity to have cumbersome trays or special furniture become things of the past. Playing on the floor and outdoors encourages independence for the child, leaving parents and carers free to continue with family socialising and household tasks, knowing that their child can move freely at will. With most activities pressure to assist is reduced merely to supervising normal play and development.

The highly manoeuvrable Bobcat DX enables children to determine their own activities without asking or waiting for assistance. Simultaneous development, emotional and physical, with their able bodied peer group removes the inevitable frustration which would otherwise set in.

Transporting the Bobcat DX presents no difficulty with the easily removable seat, remote drive panel and compact size of the unit.

Benefits include:

- QED offers a wide range of seating options.
- Dynamic DX control system enables the Bobcat DX to be used successfully within the school, home or outdoor.
- Three dimensional movement reduces the need for carer participation in many activities.
- Easy 'break-down' for transport in the back of estate car.
- Accessories available including trays, lights and indicators and ramps.
- Suitable for users up to 12 stone (75kg) in weight.

Mark N Millaeus

(Division Sign-Off) for CMW
Division of General Restorative Devices
510(k) Number K970543

Over-the-Counter Use X