K023005

9. 510(k) SUMMARY

9.1 Submitter's Name and Contact Information

Submitter Company: Bell, Boyd & Lloyd, LLC
Address: 70 W. Madison St. Suite 3300
City, State, Zip Chicago, IL 60602

OCT 18 2002

Contact Person: Name: Richard O. Wood
Phone/Fax: (312) 807-4364
(312) 827-8189 (Fax)
Email: rowood@bellboyd.com

Date Prepared: Date: September 5, 2002

9.2 Name of Device and Name/Address of Applicant

Aquilla Model Wheelchair

Haywood Vocational Opportunities, Inc.
56 Scates St.,
Waynesville, N.C. 28786,

9.3 Name and Address of Manufacturer

Remploy Mobility
Jubilee Industrial Estate,
Ashington,
Northumberland,
United Kingdom NE63 8UE
01670 813718
01670 851990 (Fax)

9.4 Common or Usual Name

Mechanical wheelchair

9.5 Classification Name

Wheelchair, mechanical

9.6 Predicate Device

The Aquilla wheelchair is substantially equivalent to the Breezy® 510 model wheelchairs manufactured by Sunrise Medical (K974820, 1/27/1998).

9.7 Intended Use

The Aquilla Modular Wheelchair is intended to provide mobility for occupants who are unable to walk or have difficulty in walking without assistance.

9.8 Technological Characteristics and Substantial Equivalence

9.8.1 Device Description

The Aquilla Modular Wheelchair is manually operated, and can be configured for propulsion by an attendant or an occupant. The range of sizes and build configurations are suitable for male or female sizes from junior to adult.

The Aquilla Modular Wheelchair consists of typical components found on most manual wheelchairs. The chairs feature a backrest, folding seat frame, footrest, rear wheels and front castors. Accessories include occupant-positioning belts, and optional features which allow a chair to be changed simply to meet the changing environmental and health requirements of the occupant.

Aquilla is suitable for use both indoors and outdoors on surfaces that are intended typically for public access. This type of wheelchair is not suitable for soft and undulating terrain or for climbing obstacles. Aquilla can be easily folded for compact storage, and armrests and footrests can be removed to reduce the weight for lifting.

Aquilla is labeled to indicate important aspects of use, including warnings and cautions.

9.8.2 Substantial Equivalence

The Aquilla Modular Wheelchair is substantially equivalent to the Breezy® 510 wheelchair manufactured by Sunrise Medical (K974820, 1/27/98). They are both lightweight wheelchairs with the intended use of providing mobility to occupants unable to walk or have difficulty in walking without assistance.

9.9 Performance Data

The Aquilla wheelchair has been tested to and met the following ISO requirements: ISO 7176-1, -3, -5, -7, -8, -15, -16, -19.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2002

Haywood Vocational Opportunities
Bell, Boyd & Lloyd, LCD
c/o Richard O. Wood
70 W. Madison Street, Suite 3300
Chicago, Illinois 60670

Re: K023005
Trade/Device Name: Aquilla Modular Wheelchair
Regulation Number: 890.3850
Regulation Name: Wheelchair, mechanical
Regulatory Class: Class I
Product Code: IOR
Dated: September 4, 2002
Received: September 9, 2002

Dear Mr. Wood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Milhorn

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

Enclosure

510(k) Number (if known): _____

Device Name: Aquilla Modular Wheelchair

1. INDICATIONS FOR USE:

Aquilla Modular Wheelchair:

The Aquilla Modular Wheelchair is intended to provide mobility for occupants who are unable to walk or have difficulty in walking without assistance.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023005

Prescription Use _____ OR Over-The-Counter Use ____X____

(Optional Format 1-2-96)