K043332

DEC 13 2004

7. 510(k) summary

510(k) Summary

Aerospace Industrial Development Corporation's

AIDC 8500-II Wheelchair

Sponsor's information:

Cycling and Health Tech Industry R&D Center

No. 17, 37th Rd., Taichung Industry Park, Taichung, Taiwan

Contact person: Jeff Chang

Director of Testing Department

Phone: 886-4-23501100

Facsimile: 886-4-22430627

e-mail: jeff-chang@umail.hinet.net

Date prepared: November 12, 2004

Proprietary and Manufacturer information:

Aerospace Industrial Development Corporation (AIDC)

111-X60, Lane 68, Fu-Hsing N. Rd., Taichung, Taiwan

Contact person: Zen-Jye Chen

Manager of Medical Device Section

Phone: 886-4-22842291

Facsimile: 886-4-22842849

e-mail: zenjyechen@ms.aidc.com.tw

Device

Trade name: AIDC 8500-II Wheelchair

Common name: Manual Wheelchair

Classification name: Mechanical wheelchair

Medical specialty (Panel): Physical Medicine Device

Regulation number: 890.3850

Product Code: 89IOR

Classification: Class I

Predicate devices

Manufacture name: Invacare Corporation

Name: Solara Jr. Wheelchair

k number: K012370

Date cleared: 8/3/2001

Intend use of device

AIDC 8500-II Wheelchair is a tilt-in-space mobile positioning system for everyday indoor and outdoor use on flat terrain. They are available in a range of sizes to accommodate a particular fit to the user.

AIDC 8500-II Wheelchair can be an attendant propelled or self propelled device, its intended use is to enhance mobility to physically challenged persons limited to a sitting position on the flat and firm terrain in outdoor or indoor. It has various options to control and/or support the user's specific needs.

Device description:

The AIDC 8500-II Wheelchair is manually operated mechanical wheelchair. It is designed to be light in weight with folding frame. The range of sizes and configurations are available to accommodate the needs of each user. The wheelchair is suitable to provide mobility to user for both indoors and outdoors with firm surface that is free of climbing obstacles.

The AIDC 8500-II Wheelchair consists of typical components found on most manual wheelchair. The wheelchair consists of aluminum alloy frame constructed of AA6061-T6 aluminum alloy tubing that is TIG-welded, removable seat and back upholsteries, flip-up available footrest and legrest, front castors and rear wheels.

The owner's manual of AIDC 8500-II Wheelchair provides information on warnings, cautions and operation instruction of the wheelchair.

Substantial equivalence:

The AIDC 8500-II wheelchair is substantially equivalent to the Solara Jr. Wheelchair (K012370) manufactured by Invacare Corporation.

Analysis of comparison of design, function and feature of AIDC 8500-II wheelchair to Solara Jr. Wheelchair (K012370), together with the results of compliance testing to existing ANSI/RESNA, ISO 7176 standards, demonstrate the device to be substantially equivalent to the predicate in terms of meeting performance criteria and functioning as intended.

While there are minor differences in performance specifications of the wheelchairs, these differences do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness. Therefore, AIDC believes that the AIDC 8500-II wheelchair is substantially equivalent to legally marketed devices currently in commercial distribution.

Non-Clinical testing

AIDC 8500-II wheelchairs have been tested to wheelchair standards. They include:

(1). ANSI/RESNA WC Vol. 1 Sec. 1 Determination of static stability
(2). ANSI/RESNA WC Vol. 1 Sec. 5 Determination of overall dimensions, mass and turning space
(3). ANSI/RESNA WC Vol. 1 Sec. 7 Measurement of seating and wheel dimensions
(4). ANSI/RESNA WC Vol. 1 Sec. 8 Static, impact and fatigue strengths
(5). ANSI/RESNA WC Vol. 1 Sec. 15 Requirements for the information disclosure, documentation, and labeling
(6). ANSI/RESNA WC Vol. 1 Sec. 16 Resistance to ignition of upholstered parts
(7). ISO7176-1 Determination of static stability
(8). ISO7176-5 Determination of overall dimensions, mass and turning space
(9). ISO7176-7 Measurement of seating and wheel dimensions
(10). ISO7176-8 Static, impact and fatigue strengths
(11). ISO7176-15 Requirements for the information disclosure, documentation, and labeling
(12). ISO7176-16 Resistance to ignition of upholstered parts
(13). ISO 7176-19 Wheeled mobility devices for use in motor vehicles
(14). California Bureau of Home Furnishings 117 Flammability Standards

Conclusion

Analysis of comparison of design, function and feature of AIDC 8500-II Wheelchair to Invacare Solara Jr. Wheelchair, together with the results of compliance testing to existing ANSI/RESNA and ISO 7176 standards, demonstrate the device to be substantially equivalent to the predicate in terms of meeting performance criteria and functioning as intended.

The AIDC 8500-II Wheelchair is substantially equivalent to the predicate device and does not raise any issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2004

Cycling and Health Tech Industry R&D Center
C/o Mr. Zen-Jye Chen
Manager of Medical Device Section
Aerospace Industrial Development Corporation (AIDC)
111-X60, Lane 68
Fu-Hsing N. Rd., Taichung
Taiwan

Re: K043332
Trade/Device Name: AIDC 8500-II Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: November 12, 2004
Received: December 2, 2004

Dear Mr. Chen:

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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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. Melkerson

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

3. Device descriptive information

3.1 Statement of indication for use

Statement of Indications for Use

510(k) Number (if known): K043332

Device Name: **AIDC 8500-II Wheelchair**

Indications for Use:

AIDC 8500-II Wheelchair is intended use to provide mobility to physically challenged persons limited to a sitting position on the flat and firm terrain in outdoor and indoor.

Prescription Use ✓ Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) AND/OR

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

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

for Mark N Milhern

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

510(k) Number K043332

(Posted November 13, 2003)