K080207

Danyang Huayi Medical Equipment & Supply Co., LTD
One Zhenxing Road, Yunyang Economical Development Zone, Jiangsu Province, 212300 CHINA
Tele: 86511-86900809; Fax: 86511-86900805

SUMMARY OF SAFETY AND EFFECTIVENESS

ADMINISTRATION INFORMATION

MAR 12 2008

SPONSOR IDENTIFICATION
Danyang Huayi Medical Supply and Equipment Co., LTD
No. 1 Zhenxing Road, Yunyang Economical Development
Zone, Danyang City, Jiangsu Province, 212300, CHINA
Contact Person: Mr. Tomy Tang
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ESTABLISHMENT REGISTRATION NUMBER: 3006534178

OFFICIAL CONTACT PERSON
Norman F. Estrin, Ph.D.
President
ESTRIN CONSULTING GROUP, INC.
9109 Copenhaver Drive
Potomac, MD 20854
Tel: (301)279-2899
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estrin@yourFDAconsultant.com

DATE OF PREPARATION OF THIS SUMMARY: January 19, 2008

PROPRIETARY (TRADE) NAME: Danyang HUAYI K7 Wheelchair

COMMON NAME: Wheelchair

CLASSIFICATION NAME: Wheelchair, Mechanical

REGULATION NUMBER: 21 CFR 890.3850

PROPOSED REGULATORY CLASS: Class I

MEDICAL SPECIFICATIONS: Physical Medicine

DEVICE PRODUCT CODES: 89 IOR

DESCRIPTION OF DEVICE:
The Danyang Huayi K7 wheelchair is a wheelchair that provides mobility to persons limited to a sitting position. It consists of rigid, mechanical, steel frame and nylon upholstery back and seat that meet ISO 7176-16: Resistance to ignition of Upholstered parts. It has two 24" rear wheels and two 8" front casters for turning and maneuverability. The Danyang Huayi K7 wheelchair is intended for the use in indoors and outdoors, over smooth surface (all standard indoor flooring surfaces, concrete, asphalt and pocked dirt) that free of large obstacles and inclines greater than 9 degrees.

INDICATION FOR USE
The Danyang Huayi K7 wheelchair is indicated for providing mobility to persons limited to a sitting position.

CONFORMANCE TO STANDARDS
The Danyang Huayi K7 wheelchair production meets the following standards:

- ISO 7176-1 Wheelchair: Determination of static stability
- ISO 7176-3 Wheelchair: Determination of efficiency of brakes.
- ISO 7176-5: Determination of overall dimension, mass and turning space.
- ISO 7176-7: Measurement of seating and wheel dimensions.
- ISO 7176-8 Wheelchair: Requirements and test methods for static, impact and fatigue strengths.
- ISO 7176-11 Wheelchair: Test dummies
- ISO 7176-13: Determination of friction of test surface.
- ISO 7171-15 Wheelchair: Requirements for information disclosure, documentation and labeling.
- ISO 7171-16 Wheelchair: Resistance to ignition of upholstered parts – requirements and test methods.

PREDICATE DEVICE: Invacare Tracer IV Manual Wheelchair (K935398)

SUBSTANTIAL EQUIVALENCE: The Danyang Huayi K7 wheelchair and Invacare Tracer IV Manual Wheelchair (K935398) are substantially equivalent products in all areas impacting safety and effectiveness.

CONCLUSION: The Danyang K7 wheelchair raises no safety/efficiency issues or makes any claims that differ from the predicate device cited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2008

Danyang Huayi Medical Supply & Equipment
% Estrin Consulting Group, Inc.
Dr. Norman F. Estrin
9109 Copenhaver Drive
Potomac, MD 20854

Re: K080207
Trade/Device Name: Danyang Huayi® K2 and K7 Wheelchairs
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: January 20, 2008
Received: February 5, 2008

Dear Dr. Estrin:

This letter corrects the substantially equivalent letter dated March 12, 2008.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080207

Device Trade/Proprietary Name: Danyang Huayi® K7 Wheelchair
Indications for Use:

The Danyang Huayi® K7 Wheelchair is indicated for providing mobility to persons limited to a sitting position.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K080207 000012

Indications for Use

510(k) Number (if known): K080207

Device Trade/Proprietary Name: Danyang Huayi® K2 Wheelchair
Indications for Use:

The Danyang Huayi® K2 Wheelchair is indicated for providing mobility to persons limited to a sitting position.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKM

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

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510(k) Number K080207