HEARTWAY MEDICAL PRODUCTS CO., LTD.

NO. 4, ROAD 5, TAICHUNG INDUSTRIAL PARK,
TAICHUNG, TAIWAN R. O. C.
TEL:886-4-3580357 (Sales Dept.)
886-4-3583232 (Rep.)
FAX:886-4-3590786

Internet: http://www.webtree.net.tw/heartway/
E-mail: heartway@webtree.net.tw

DEC - 4 1997

K973491

Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
Food & Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

Dear Sir or Madam,

In accordance with the requirements of section 510(k) of the Federal Food and Drug Cosmetic Act we hereby request to register for commercial distribution for the following device.

Device Name ----------Mechanical Folding Wheel Chair
Common Name ----------Standard Folding Wheel Chair
Heartway Models----------H1 through H10(Sea Exhibit I)
Proprietary Name ----------Not yet Determined
Established Registration No.----------903564
FDA Classification----------Class I

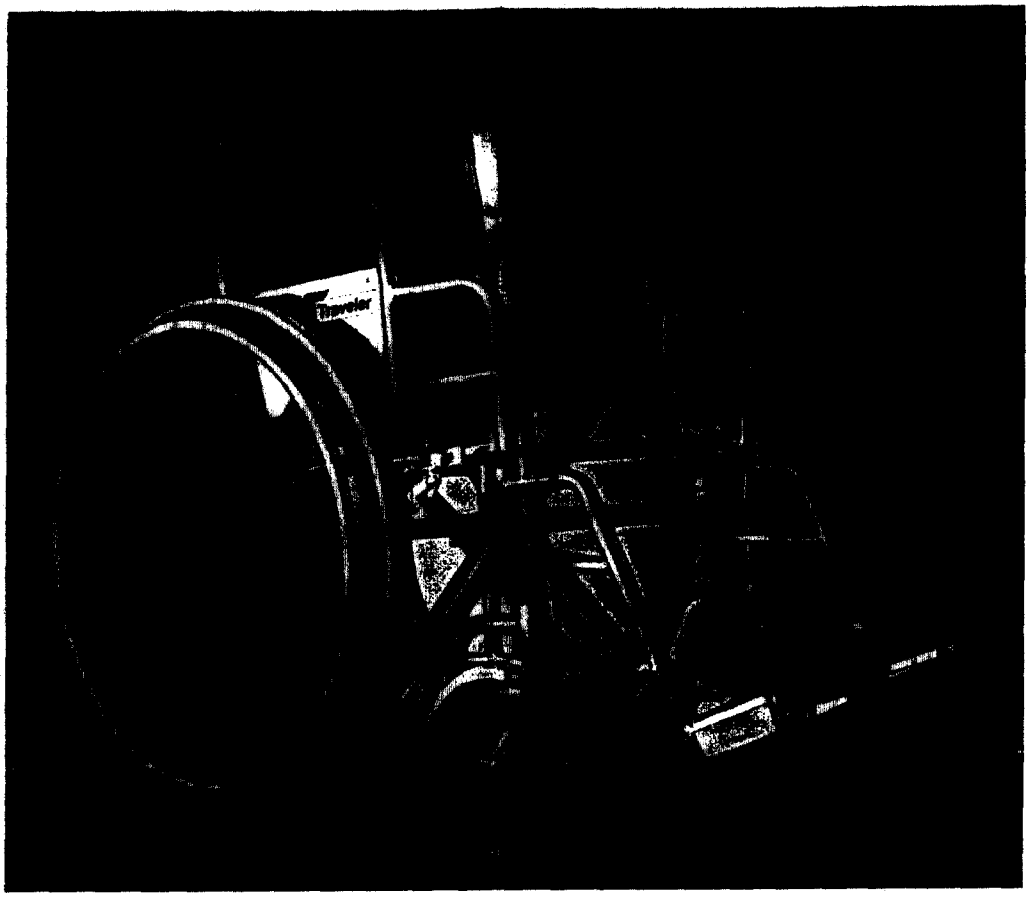
Summary

The design and construction of this device is such that it presents a mobility unit allowing users to be transported by an attendent or to be self propelled. This device is intended to provide mobility to invalids who are otherwise incapable of ambulation with patient ambulatory assist devices.

The wheelchairs listed above are substantially equivalent to many products being Marketed at this time. Wheelchairs of this type compare with the Invacare Tracer Plus Series (See Exhibit II) and the Everest & Jennings Traveler Series (see Exhibit III)

EXHIBIT III (2 PAGE
①

New Traveler™



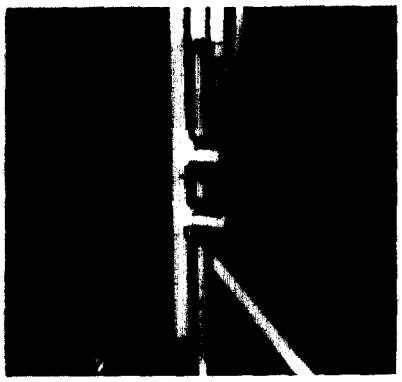
TRAVELER QUALITY AND DURABILITY. . . Ever evolving to meet the needs of our customers, the "New" Traveler enhances its reputation as the rental wheelchair of choice. Now available with dual rear axle positioning for seat heights from 17-3/4" to 19-3/4", seat widths from 16" to 22" wide and a weight capacity of up to 300 pounds. The Traveler has earned its reputation for enduring the rigors of all types of use. . . **designed to survive the journey.**

- **Dual axle positioning...seat heights between 17-3/4" and 19-3/4".**
- **Front slide post design provides added rigidity and easy folding.**
- **Reinforced top inner rail for extra strength.**
- **Strong upholstery inner liner tested at 350 lbs. per inch, lasts twice as long as comparable models.**
- **Low-maintenance, reinforced molded wheels with snap-on solid tires.**
- **Desk length or full length arms available for easy transfer and access.**
- **Superior E&J cam-action footrest design combined with quality manufacturing provide a snug fit and a true swing-away motion.**
- **300 lb. capacity on 20" and 22" wide models.**
- **2 year limited warranty on frame and crossbraces.**

Everest & Jennings®

Value through Innovation

New Traveler™



DUAL AXLE BUSHINGS
Allows for easy seat conversion of seat heights from 17-3/4" to 19-3/4" through use of different wheels and caster combinations.

FEATURES

- Padded, double-embossed burgundy leatherette upholstery and padded armrests.
- Durable 24" x 1" black molded wheel with snap-on rubber tire.
- 8" x 1" black molded front casters.
- Rugged cam-action swing-away detachable footrests or elevating legrests.
- Durable aluminum footplate.
- Choice of 3 frame styles: std. fixed arm, Std/Hemi/Extra wide detachable arm and Std/Hemi recliners.
- Available with a variety of optional arm styles.

All specifications subject to change without notice.

"New" Traveler™ Dimensions and Weights (inches and pounds)

"New" Traveler Models	SEAT			ARMS			BACK	OVERALL				EXTENSIONS				WT.*
												FOOTRESTS		LEGRESTS		LBS.
												MIN	MAX	MIN	MAX	
Fixed Arm, Narrow Adult	16	16	193/4	141/4	101/8	301/4	161/2	30	36	221/2	11	161/2	22	16	23	35
Fixed Arm, Adult	18	16	193/4	161/4	101/8	301/4	161/2	30	36	241/2	11	161/2	22	16	23	36
Detachable Arm, Narrow Adult, Hemi	16	16	173/4	161/4	93/4	267/8	161/2	30	36	241/4	11	161/2	20	16	23	40
Detachable Arm, Adult, Hemi	18	16	173/4	181/4	93/4	267/8	161/2	30	36	261/4	11	161/2	20	16	23	41
Detachable Arm, Narrow Adult	16	16	193/4	161/4	93/4	287/8	161/2	30	36	241/4	11	161/2	22	16	23	40
Detachable Arm, Adult	18	16	193/4	181/4	93/4	287/8	161/2	30	36	261/4	11	161/2	22	16	23	41
Detachable Arm Narrow Adult Recliner	16	17	193/4	161/4	93/4	287/8	233/8	36	531/8	241/4	13	161/2	22	15	21	55
Detachable Arm, Adult Recliner	18	17	193/4	181/4	93/4	287/8	233/8	36	531/8	261/4	13	161/2	22	15	21	55
Detachable Arm Adult-Wide (20")	20	16	193/4	201/4	93/4	287/8	161/2	30	36	281/4	113/4	161/2	22	16	23	47
Detachable Arm Adult-Extra Wide (22")	22	16	193/4	221/4	93/4	287/8	161/2	30	36	301/4	113/4	161/2	22	16	23	48

All dimensions are + or - 1/4" "Without front rigging.

NOTE: Everest & Jennings maintains the policy of continual product improvement, therefore we reserve the right to make changes without notice.

Everest & Jennings®
Value through Innovation

United States
4203 Earth City Exprswy
St. Louis, MO 63045

For additional information call
1-800-235-4661

Canada
111 Snidecroft Road
Concord, Ontario,
Canada
L4K 2J8

For additional information call
1-905-669-2381

Mexico
Calle 3 No. 631
Zona Industrial
Codigo Postal 44940
Guadalajara, Jalisco
Mexico

For additional information call
(011) 52-36-12-12-34

PN# 02003023 7/96
Printed in the USA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kenny Ho
President
Heartway Medical Products Company, Limited
Number 4, Road 5, Taichung Industrial Park
Taichung, Taiwan R.O.C.

DEC - 4 1997

Re: K973491
Mechanical Folding Wheelchair
Regulatory Class: I
Product Code: IOR
Dated: October 27, 1997
Received: October 31, 1997

Dear Mr. Ho:

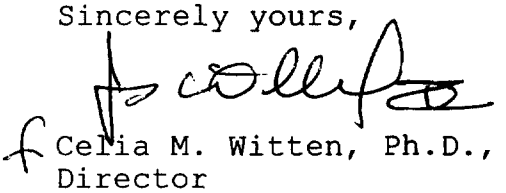
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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,



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

510(k) Number (if known): K973491

Device Name: STANDARD FOLDING WHEELCHAIR

Indications For Use:

The design and construction of this device is such that it presents a mobility unit allowing users to be transported by an attendent or to be self propelled. This device is intended to provide mobility to invalids who are otherwise incapable of ambulation with patient ambulatory assist devices.

The models to be offered are of different sizes allowing for user preferance because of physical needs. Options for users include removeable armrests & detachable footrests to accomodate user requirements.

(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 K973491

Prescription Use____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)