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FDA/CDRH/ODE/DNC

SECTION IV
510(k) SUMMARY of
SAFETY AND EFFECTIVENESS
Prepared on August 28, 1997

Submitted By:
Jaken Co., Inc.
2346 E. Walnut Ave
Fullerton, Ca., 92831
Contact: Samantha Lin

Device Identification

Trade/Proprietary Name - Elite Lightweight Wheelchair

Generic Name - wheelchair (non-powered)

Classification of the Predicate Device - Class III

Intended Use

The above referenced device is a lightweight mechanical wheelchair used by those who are immobile to transport from one location to another. This device submitted for FDA review and is equivalent to Everest and Jennings Lightning Wheelchair. Our device and the predicate device provide the same function for occupants who are unable to move due to injuries or other medical conditions.

Description of Device

The frame of our Elite wheelchair is made from a high strength tensile steel called chromoly which is 28% lighter than the usual standard chrome-plated frame wheelchairs. The frame of the wheelchair is coated with a durable powder coated finish of blue, burgandy or black. It is a rigid frame that comes in two different arm styles: Fixed Full Length or Removable Wrap-Around Desk Length. Both arm styles come with padded arms. The 24" wheels can be spoke aluminum rear wheels with pneumatic tires or mag wheels with hard rubber tires. Seat width on the wheelchair is either 18" or 16". The seat material is nylon spill proof upholstery. The rigging on the wheelchair is Cam-Action Swing Away Detachable Footrests or Detachable Elevating Legrests with calf pads that are padded for more comfort. Footplates are of aluminum material.

Dimension :

Overall Length without rigging: 31"

Overall Width (opened): Between 25"-26"

Overall Width (closed): Between 10.5"-11.5"

Gross Weight without rigging: Between 29-30.5 lbs

Since this wheelchair is non-powered there are two ways to propel the device, 1) is to have an assistant push the wheelchair from the back where the hand grips are or 2) if the occupant has mobility with their upper half of the torso he or she can use their arms on the handrims that are attached to the 24" wheel to self-propel themselves. The wheelchair is fully assembled and is packaged in a closed position in the wheelchair box. The only assembly required is the Rigging. Following is the instruction for the rigging.

Device Description Continue

- A. **Swing Away Footrest:** Place the rigging on the mounting post that is welded to the wheelchair and swing the footrest closed (No assembly required on this particular rigging). You will here a click which indicates the rigging is in place for use.
- B. **Swing Away Elevating Legrest:** See Appendix I which shows how to assemble the Elevating Legrest. To install onto the wheelchair, please follow the same procedure as the Swing Away Footrest.

As seen in Appendix II the comparison chart show the overall features of the Elite wheelchair versus the Lightning including the various styles available to the enduser.

The Lightning Wheelchair equivalent to the Premier 2 (both are manufactured by Everest and Jennings) is a legally marketed device which has been granted marketing clearance by FDA following the submission of a 510(k) number which is K930412. Please see Appendix III for photographs and diagram of the two devices.

The Elite wheelchair can travel on any hard surfaces such as carpet, tile or concrete flooring.

The maximum weight bearing capacity is 250 lbs.

A tiltover test is not applicable for the Elite wheelchair submitted for review.

Steel Material

Material Frame: CR-MO AP (Chromaly)

Chemical Compositions: Chromium 0.85%-1.25%, Carbon 0.12% - 0.18%, Magnesium 0.55% - 0.90%, Phosphorus 0.30%, Sulfur 0.30%, Silicon 0.15% - 0.35%, Molybdenum 0.15% - 0.35%.

Material Strength tests:

Tube Size: 22.2mm * 1.0mm

Outside Diameter Tube: 22.16mm - 22.17mm

Tube Thickness: 1.01mm - 1.03mm

Tube Straightness: .07mm - .12mm

Hardness: 80.5mm - 80.0mm

Elongation: 35mm - 36mm

Tension Strength: 56.3mm - 56.8mm

Yield Strength: 33.3mm - 33.0mm

The Eddy Current test was completed on the material.

Upholstery Material

The foam on the Upholstery was tested by SGS. The test was done in compliance with California Technical Bulletin 117 1) Section A, Part I. and 2) Section D, Part II. The test results are attached. The conclusion is that the sample submitted complies with the requirements of Section A, Part 1 and Section D, Part II for resilient Cellular Materials of California Technical Bulletin 117.

Material on Wheels

-24 Rear Wheels-

Material : Nylon 80%, Fiber 20%

-Property of Plastic Rims-

<u>Property</u>	<u>Test Method</u>	<u>Value</u>
Ash Content	*****	20.4%
Izod Impact Strength (Notch, 23deg C)	ASTM D-256	KG-CM/CM
Tensile Strength at Break	ASTM D-638	KG/cm ²
Flexural Strength	ASTM D-790	KG/cm ²
Flexural Modulus	ASTM D-790	KG/cm ²

-8" Front Casters-

Material for Plastic Rim - High Impact P.P.

Material for Tire - Thermoplastic Elastomers 100%

-Property of Caster-

<u>Property</u>	<u>Test Method</u>	<u>Value</u>
Flow Rate	ASTM D-1238	5 g/10min
Density	ASTM D-792	0.892 g/cm ³
Tensile Strength at Break	ASTM D-638	268 kg/cm ³
Elongation	ASTM D-638	9.8%
Temperature of Deform	ASTM D-648	83 deg C 4.6 kg/cm ³
Izod Impact Strength (23 deg C Notch)	ASTM D-256	9.5 kg-cm/cm

Labeling

Appendix IV shows sample packaging

Appendix V shows labeling on the wheelchair

Appendix VI shows Operators Instruction



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 1997

Ms. Samantha Lin
Jaken Company, Inc.
2346 East Walnut Avenue
Fullerton, California 92831

Re: K974197
Elite Lightweight Wheelchair
Regulatory Class: I
Product Code: IOR
Dated: June 21, 1997
Received: November 7, 1997

Dear Ms. Lin:

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.

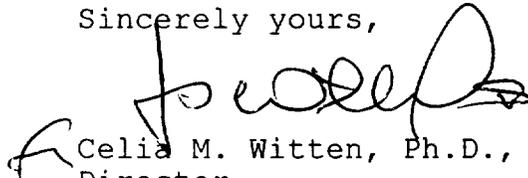
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Samantha Lin

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,



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): K972730

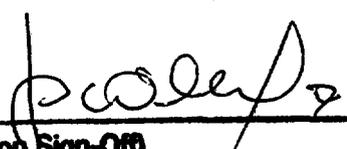
Device Name: ELITE SERIES WHEELCHAIR

Indications For Use:

OUR ELITE LIGHTWEIGHT WHEELCHAIR IS A MECHANICAL DEVICE THAT TRANSPORT OCCUPANTS WHO ARE IMMOBILE FROM ONE LOCATION TO ANOTHER. IN ORDER FOR ONE TO OPERATE THIS DEVICE AN ASSISTANT CAN PUSH THE WHEELCHAIR FROM BEHIND USING THE HANDLE BARS OR IF THE OCCUPANT HAS FUNCTION OF HIS/HER UPPER TORSO THEY CAN WHEEL THEMSELVES AROUND BY USING THE HANDRIMS THAT IS ATTACHED TO THE WHEELS.

(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 474197

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X