

**Assembly Required Distributors Inc.**

3 Crabapple Lane  
Commack, NY 11725-2405  
Phone/fax 516-864-9575

12973418

September 5, 1997

**510K Summary**

Submitter: Assembly Required Distributors Inc.  
3 Crabapple Lane  
Commack, NY 11725  
516-864-9575

Contact Person: Doreen Murphy

Date of Preparation: 9/8/97

Trade/Proprietary Name: Transport Plus and Transport Deluxe

Common/Usual Name: Manually Propelled Transport Wheelchair

Legally Marketed Device: Everest & Jennings model Universal wheelchair – K930411  
For Equivalence Invacare model Rolls 2000 wheelchair – K881762

Device Description: Wheelchair to be a manual transport device, with 8” front swivel casters on the front, and 24” mag style wheels on the rear. Wheelchair will be foldable for storage, will be chrome plate Finnish. Armrests will be padded or plastic and will have padded embossed upholstery for user comfort. Wheelchair will be equipped with wheel locks to prevent rolling while transferring patient. Push handles will be of a non-slip vinyl material. Standard color available will be dark blue. Chairs to have rear extensions to prevent tip-over. Wheelchairs to be available in models with swing away footrests or elevating legrests as shown in pictures.

Intended Use: Predicate manual wheelchair use is stated to allow user, or user assistant to propel or push chair in order to maneuver seated individual in a safe, controlled environment. Also must be able to lock rear wheels for patient transfer. Subject wheelchair is to have same functionality.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT -9 1997

Ms. Doreen Murphy  
Compliance Officer  
Assembly Required Distributors, Inc.  
3 Crabapple Lane  
Commack, New York 11725-2405

Re: K973418  
Trade Name: Transport Plus and Transport Deluxe  
Regulatory Class: I  
Product Code: IOR  
Dated: September 8, 1997  
Received: September 10, 1997

Dear Ms. Murphy:

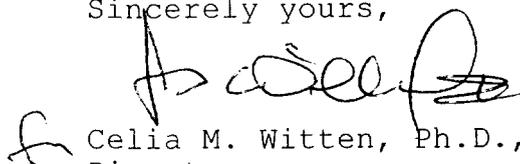
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



f 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

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Over-the-Counter Use \_\_\_\_\_

*X*

*[Signature]*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number \_\_\_\_\_

*K97*