1 OF 2
K030250

510(k) Summary

Submitters Name and Address

Independence Technology, L.L.C.
45 Technology Drive
P.O.Box 4917
Warren, NJ 07059 – 4917

MAR 0 4 2003

Contact Person

James P. O'Donnell
Vice President, Regulatory Affairs
Independence Technology, L.L.C.
45 Technology Drive
P.O.Box 4917
Warren, NJ 07059 – 4917
908 – 412 – 2266
jodonnel@indus.jnj.com

Date Prepared

January 22, 2003

Name of Device

INDEPENDENCE(TM) iGLIDE(TM) Manual Assist Wheelchair

Classification Name

Wheelchair, Powered

Identification of Predicate Device

TAILWIND Power Assist Wheelchair

Description of Device

The INDEPENDENCE(TM) iGLIDE(TM) Manual Assist Wheelchair is the TAILWIND Power Assist Wheelchair. With each push on the handrims, sensors and controllers calculate the difference between the effort on the handrims and the force needed to propel the chair. Electric motors supply the auxillary power needed to negotiate varying surfaces with virtually no change in effort.

The device drive consists of a gearbox with a motor and a motor controller for each side of the chair and a battery mounted underneath the chair. An on/off switch, located on the underside of the seat turns the unit on/off.

Intended Use

The INDEPENDENCE(TM) iGLIDE(TM) Manual Assist Wheelchair is intended to provide mobility to persons limited to a seated position that are capable of operating a manual or power wheelchair.

Comparison to Predicate Device

The INDEPENDENCE(TM) iGLIDE(TM) Manual Assist Wheelchair **is the** TAILWIND Power Assist Wheelchair. The only differences between the two devices are the trade name, company name and the existence of the Prescription Device Statement in the labeling. The INDEPENDENCE(TM) iGLIDE(TM) Manual Assist Wheelchair does not have the Statement, the TAILWIND Power Assist Wheelchair does have the Statement.

Non-Clinical Tests Performed

Because the new and predicate devices are the same device, no new testing is needed.

Summary

The INDEPENDENCE(TM) iGLIDE(TM) Manual Assist Wheelchair **is the** TAILWIND Power Assist Wheelchair. The removal of the Prescription Device Statement does not raise any questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 4 2003

Mr. James P. O'Donnell
Vice President, Regulatory Affairs
Independence Technology, L.L.C.
45 Technology Drive
P.O. Box 4917
Warren, NJ 07059-4917

Re: K030250
Trade/Device Name: iGlide™ Manual Assist Wheelchair
Regulation Number: 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: January 23, 2003
Received: January 24, 2003

Dear Mr. O'Donnell:

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.

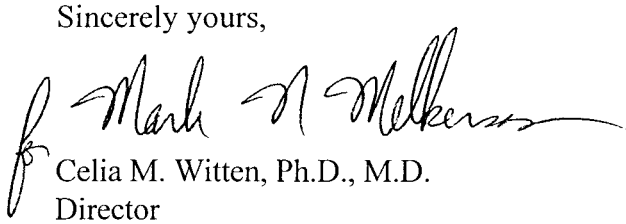
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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,



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

510(k) Number (if known): K030250

Device Name: iGlide™ Manual Assist Wheelchair

Indications For Use:

The INDEPENDENCE™ iGlide™ Manual Assist Wheelchair is intended to provide mobility to persons limited to a seated position that are capable of operating a manua or power wheelchair.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

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

510(k) Number K030250

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

(Optional Format 1-2-96)