AUG 27 2002

K022704

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CONFIDENTIAL DOCUMENT

DELTAGLIDE
power for people

510(k) Summary

Submitter's Name and Address
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Contact Person
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DeltaGlide, Inc.
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Date Prepared
June 7, 2002

Name of Device
TAILWIND

Classification Name
Wheelchair, Powered

Identification of Predicate Device
Sunrise Medical Model Quickie 2 Power Assist Wheelchair (K001491)

Description of the Device
The TAILWIND power assist wheelchair is a light duty, conventional, rear wheel drive, rigid wheelchair. The TAILWIND wheelchair incorporates power assist components with a typical manual wheelchair. As a motorized wheelchair, it contains motors, drive wheels, and batteries.

The wheelchair is propelled using a mix of human power to manually turn the chair wheels; this action activates the power assist electric motors to provide a short burst of supplementary power.

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Intended Use
The TAILWIND power assist wheelchair empowers physically challenged persons by providing a means of enhanced mobility.

Comparison to Predicate Device
The device (Tailwind Wheelchair) has similar technological characteristics as the predicated device (Sunrise Medical Model Quickie 2 Power Assist Wheelchair). The device and the predicate are typical manual wheelchair frames; they use aluminum and steel in their frames and components, and standard material and covers for the back upholstery and cushions. Microprocessors are used. Motors employ direct electrical current with rechargeable batteries for an energy source. The operating speeds and maneuverability are equivalent, and the wheelchairs are recommended for indoor and light outdoor use. Standard accessories and components are common.

Both devices use a mix of human and electrical power to propel the wheelchair. Both devices are controlled (steering, braking and accelerating) by means of the handrims. Both devices can be used with the power units turned off. Both devices use conventional wheel locks.

Non-Clinical Tests Performed
All applicable tests were voluntarily conducted in accordance with ISO 7176, including Parts 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 14, 16, and 21. Where applicable a 100 kg dummy (plus 13.4 kg) as specified in ISO 7176 – 11 was used.

Summary
The TAILWIND power assist wheelchair is substantially equivalent to the Sunrise Medical Model Quickie 2 Power Assist Wheelchair in design, function, and features. As shown by the non-clinical testing, any differences between the TAILWIND power assist wheelchair and the predicate device do not raise any questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2002

DeltaGlide, Inc.
c/o Mr. Heinz Joerg Steneberg
Division Manager, Medical Division
TUV Rheinland of North America, Inc.
12 Commerce Road
Newton, CT 06470

Re: K022704
Trade/Device Name: Tailwind
Regulation Number: 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: July 16, 2002
Received: August 14, 2002

Dear Mr. Steneberg:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for 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

Attachment 1: Indications for Use Form

510(k) Number (if known): K022704

Device Name: TAILWIND

Indications For Use:

The TAILWIND power assist wheelchair empowers physically challenged persons by providing a means of enhanced mobility.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhouse

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

510(k) Number K022704

(Optional Format 3-10-98)