JUN 0 3 2004

K041341

510 (K) Summary
Golden Technologies, Inc.
510 (K) Premarket Notification
Golden Spyder

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Golden Technologies, Inc.
401 Bridge Street
Old Forge, Pa. 18518
Phone: (800) 624-6374
Facsimile: (570) 451-7494
Contact Person: Gene Kulon
Official Correspondent
Date Prepared: May 18, 2004

Name of Device and Name / Address of Sponsor:

Golden Spyder

Golden Technologies, Inc.
401 Bridge Street
Old Forge, Pa. 18518
Phone: (800) 624-6374
Facsimile: (570) 451-7494

Common or Usual Name:
Power Wheelchair

Classification Name:
Wheelchair, Powered

Comparison to Predicate Devices:

The product, which is substantially equivalent to the Golden Spyder, is the Alante, (K011153). They are both controlled by the use of a joystick controller with onboard batteries and battery charger. All safety features are equivalent.

Device Description:

The Golden Spyder is a six wheeled battery powered wheelchair. It has a Dynamics Shark 60 amp controller system, which is used to operate the Golden Spyder. The one-piece base of the wheelchair is made of welded steel construction. The main frame also consists of a battery floor pan. The center drive wheels are mounted on the drive shafts of separate motor/gear assemblies, one on the left side of the wheelchair, the other on the right side. It comes standard with a removable fold down seat, which is connected, to the drive unit frame via a four-post mounting system. The seat concentrates the users weight over the center wheels to aid in traction. All seating meets California Bulletin 117 fire standards. The Golden Spyder comes standard with two easily removable 12-volt batteries and an on or off board charger. It has an operating range of 15-20 miles on a full charge. The weight capacity is 300-lbs and it has a maximum speed of 5-mph.

Intended Use:

The intended use of the Golden Spyder is to provide mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

Discussion of non-clinical tests performed for determinations of substantial equivalence are as follows:

ANSI/RESNA WC/01 1990 Determination of Static Stability Testing
ANSI/RESNA WC/02 1991 Determination of Dynamic Stability Testing
ANSI/RESNA WC/03 1990 Determination of the Effectiveness of brakes
ANSI/RESNA WC/05 1990 Determination of overall Dimensions, Mass, and Turning Space
ANSI/RESNA WC/10 1990 Determination of Obstacle Climbing Ability
ANSI/RESNA WC/Vol. 2-1998 Requirements and Test Methods for Electromagnetic Compatibility of Electric Powered Wheelchairs and Scooters.

Discussion of Clinical Tests Performed:

N/A

Conclusions:

The Golden Spyder has the same intended use and similar technological characteristics as the Alante. Moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Golden Spyder device is substantially equivalent to the predicate device.

Discussion of Clinical Tests Performed:

N/A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 3 2004

Gene R. Kulon
Golden Technologies, Inc.
401 Bridge Street
Old Forge, Pennsylvania 18518

Re: K041341
Trade/Device Name: Golden Spyder, Wheelchair, Powered
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: May 18, 2004
Received: May 20, 2004

Dear Mr. Kulon:

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,

Miriam C. Provost

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

Indications for use

510(k) Number (if known): K041341

Device Name: Golden Spyder, Wheelchair, Powered

Indications for Use:

The intended use of the Golden Spyder is to provide mobility for those persons limited to a seated position, which are capable of operating a simple hand control.

Prescription Use ____ AND/OR Over-The-Counter Use ✓
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K041341