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**MAY - 3 2004**

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

**Exhibit 3**

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: March 18, 2004

Name of Device and Name / Address of Sponsor:

**Buzzaround**

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

Common or Usual Name:  
3-Wheeled scooter

Classification Name:  
Motorized Three-Wheel Vehicle

Comparison to Predicate Devices:

The product, which is substantially equivalent to the Buzzaround, is the Companion 221, (K012258). They are both controlled by the use of a paddle type potentiometer, with onboard batteries and battery charger. All safety features are equivalent.

Device Description:

The Buzzaround is a three wheeled battery powered scooter. It has a 70-amp controller, which is used to operate the Buzzaround. The two-piece base of the scooter is made of welded steel construction. The drive unit is separable from the floor pan and includes spaced apart, differentially connected rear wheels (2) and an electric motor with a gear housing. It comes standard with a removable fold down seat, which is connected, to the drive unit frame via a pedestal and seat post concentrating the users weight over the rear wheels to aid in traction. All

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seating meets California Bulletin 117 fire standards. The Buzzaround comes standard with a compact removable 24-volt battery pack and on or off board charger and has an operating range of 10 to 15 miles on a full charge. The front and rear frames can be separated for stowage and transportation. It has intelligent electronic regenerative braking and a disc parking brake. The weight capacity is 300-lbs and it has a maximum speed of 4.5-mph

**Intended Use:**

The intended use of the Buzzaround is to provide mobility to persons limited to a seated position that are capable of operating an electric scooter.

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 Buzzaround has the same intended use and similar technological characteristics as the Companion 221. 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 Buzzaround device is substantially equivalent to the predicate device.

**Discussion of Clinical Tests Performed:**

N/A



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K041025  
Trade/Device Name: Buzzaround, Vehicle, Motorized 3-Wheeled  
Regulation Number: 21 CFR 890.3800  
Regulation Name: Motorized three-wheeled vehicle  
Regulatory Class: II  
Product Code: INI  
Dated: April 15, 2004  
Received: April 21, 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.

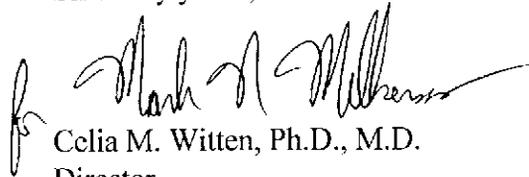
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Gene R. Kulon

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the printed name.

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

**EXHIBIT 2**

**510(k) Number (if known):** K-

**Device Name:** Buzzaround, Vehicle, Motorized 3-Wheeled

**Indications for Use:**

The intended use of the Buzzaround is to provide a lightweight scooter that offers mobility to persons limited to a seated position who are capable of operating a simple hand control.

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

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

Over-The-Counter Use   
(Optional Format 1-2-96)

OR

*[Signature]*  
\_\_\_\_\_  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K041025