



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP - 9 2004

Avner Fishbein  
Afikim Electric Vehicles  
Kibbutz Afikim 15148  
Israel

Re: K041186  
Trade/Device Name: CADDY  
Regulation Number: 21 CFR 890.3860  
Regulation Name: Powered wheelchair  
Regulatory Class: II  
Product Code: ITI  
Dated: August 6, 2004  
Received: August 13, 2004

Dear Mr. Fishbein:

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.

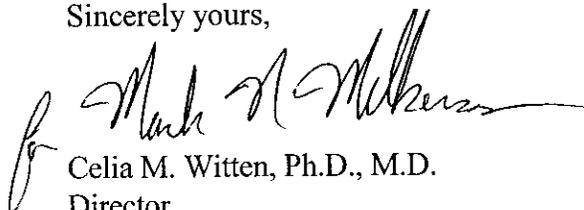
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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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 with a long horizontal flourish at the end.

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

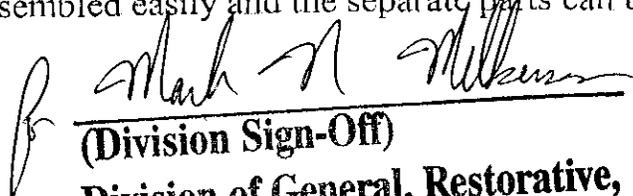
510(k) Number (if known): K041186

Device Name: CADDY

Indications for Use:

The Caddy is a transportable / foldable electric scooter. The Caddy Scooter has been developed especially for those people with mobility problems. Mobility problems are generally problems with walking or with the stamina. The Caddy is also suite for the use of elderly persons and physically disabled persons.

The Caddy scooter was developed especially for use in and around the house and to be taken along for trips. For this purpose the scooter can be folded and disassembled easily and the separate parts can be handled with ease.

  
**(Division Sign-Off)**

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

510(k) Number K041186

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   
(21 CFR 801 Subpart C)

(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)