K032879

NOV 1 3 2003

1.4. 510(k) Summary – Navigator I Powered Scooter

Submitter: **Adaptive Healthcare Technologies, Inc. - P.O. Box 614, Marstons Mills, MA 02648-0614**

Phone: 508 420-5035 **Contact Person:** Joan Johnson **Date Prepared:** June 6, 2003

Proprietary Name: Navigator I **Classification Name:** Motorized Three-wheeled Vehicle

Identification of predicate devices – Primary Predicate Device - A-BEC Mobility, Inc. Sterling Scooter (K880425), Product Code INI

SPECIFIC FEATURE	Secondary Predicate Devices RELATED TO SPECIFIC FEATURE
Steering Arm (Tiller)	Electric Mobility Corp, Rascal Convertible (K924515), Product Code INI
Parking Brakes	Amigo Sales Inc., Scooter, Motorized (K830345), Product Code INI
Anti-tip Wheels Vary Width	Amigo Sales Inc., Scooter, Motorized (K830345), Product Code INI
Rear Motor Drive System	Hoveround Corp. Hoveround MPV (K935410), Product Code ITI
Torsional Elements - Rotational Feature and Front and Rear Springs	Everest & Jennings Inc., Modular Power Base (K854051), Product Code ITI Pride Health Care Inc., JAZZY (K945936), Product Code ITI Golden Technologies Inc., Golden Eagle GT2000 (K971043), Product Code INI
Rear Caster Wheel Damper	TEFTEC Corp, OMEGATRAC (K955240), Product Code ITI
Curb Climbing	Pride Health Care Inc., JAZZY (K945936), Product Code ITI

Intended use - To provide improved mobility, both indoors and outdoors, for persons who have adequate upper body strength suitable for manual steering, and who have a medical condition that impairs their ability to stand for periods of time or to walk.

Description of the device - **Navigator I** was designed to assist individuals with limited mobility to maintain an active lifestyle. Its manual steering, high-torque four brush motor with rear wheel drive, large diameter (16") front wheels, high ground clearance (5.4"), full circle turning radius (27.5"), side to side anti-tip resistance, and curb climbing (5.5") ability make it a versatile vehicle equally adept in the shopping mall, on firm surface wilderness trails, or in the close quarters of a restaurant or home kitchen. **Navigator I** is a blended hybrid drawing elements from both scooters and wheelchairs, to meet desired features requested by long term scooter users. It does this while still maintaining the three-wheel scooter configuration with manual steering and anti-tip wheels adjacent to the single steering wheel. **Navigator I** is an electronically controlled motorized 3-wheeled vehicle employing a rear single wheel remotely steerable motor drive system (11.5" tire). It employs a 24 Volt DC permanent magnet motor powered by two 12 Volt sealed lead acid deep cycle batteries. The rigid Front Frame Assembly holds the two batteries, mounts the two front 16" diameter wheels, the two front hand controlled parking brakes, the swing up front foot rests, the electronic motor controller, and the steering arm with handle incorporating the 6-position variable speed-control. The Rear Frame Assembly is made up of the rear motor drive, the swing out Anti-tip wheels, the rear bearing block assembly and pivot wheel assembly. The Front and Rear Frame Assemblies are connected together by two semi-rigid *Torsional Elements*™ (relatively rigid to a vertical load, but allowing limited rotation), which also support the seat block mounting assembly. The *Torsional Elements*™ allow limited twist (similar to the Articulation Beam in the Pride Jazzy, K945936) to occur between the Front and Rear Frame Assemblies up to 5° of rotation, at which point one Anti-tip wheel will make contact with the ground. This greatly enhances side to side stability when driving **Navigator I** over rough terrain, since **Navigator I** is smoothly transformed from three wheels to four wheels with ground contact on all four wheels.

Substantial equivalence - The **Navigator I** design is shown to be substantially equivalent to the motorized three-wheeled scooters that were classified in class II under 21 CFR Section 890.3800. The basic three-wheeled scooter design is augmented with a patented frame design with anti-tip wheels that improve stability. **Navigator I** is a blended hybrid drawing features primarily from scooters, with some mechanical wheelchair features to improve safety and effectiveness, as outlined in the list of specific features from the predicate devices listed above and detailed in this 510(k).

Safety and effectiveness - The **Navigator I Powered Scooter** is substantially equivalent to the technology employed in the predicate devices listed in this 510(k). **Navigator I** does not raise any new issues of safety and effectiveness. The occupant initiated **swing-out anti-tip** wheels allow the occupant to readily improve resistance to side-tip and the *Torsional Elements*™ provide both a **smooth ground engagement** of the anti-tip wheels and a **side-tip warning mechanism** via front wheel pickup, which we have shown by testing to significantly improve occupant safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2003

Ms. Joan Johnson
Adaptive Healthcare Technologies, Inc.
P.O. Box 614
Marstons Mills, Massachusetts 02648-0614

Re: K032879
Trade/Device Name: Navigator I
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized tree-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: October 22, 2003
Received: October 24, 2003

Dear Ms. Johnson:

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.

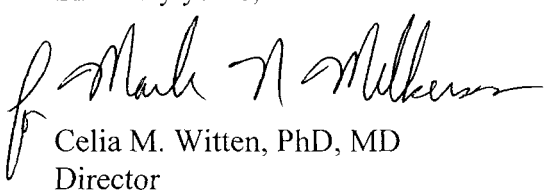
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K032879

Device Name: **Navigator I**

Indications for Use:

To provide improved mobility, both indoors and outdoors, for persons who have adequate upper body strength suitable for manual steering, and who have a medical condition that impairs their ability to stand for periods of time or to walk.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N Melkerson

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

510(k) Number K032879