OCT 20 1999

510K Summary of Substantial Equivalence

K991132

Submitted by	Mr. Thomas E. Kruse, President Hoveround Corporation, 2151 Whitfield Industrial Way, Sarasota, FL. 34243 Tel. (941) 739 - 6200 Fax. (941) 727 - 8686
Contact person	Stan Cooper
Date of Submission	March 29th 1999
Name of the Device	Activa 3 Wheeled Scooter.
Usual Name	Scooter, powered, three wheeled
Classification Name	Vehicle, Motorized, 3 Wheeled, Class 11
Regulation number	890.3800
Committee	Physical Medicine
Product Code	INI
Device Claimed to be Substantially Equivalent	"Legend" 3 wheeled scooter.
Manufacturer	Pride Healthcare
510K Number	K915659
Issue Date	01 - 21 - 92

K991132

Summary Description of Device.

The Hoveround Activa is a motorized three wheeled scooter. It is battery operated from two rechargeable lead-acid batteries. It consists of a platform which connects the three wheels, (one at the center front, one each on the rear left and right sides), an adjustable tiller and a seat for the operator.

The device can carry a sole seated operator of maximum weight 300 LB and is driven by using hand controls located at the top of the tiller, the tiller also acting to steer the vehicle.

A battery charger is provided with each model to replenish batteries.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 20 1999

Mr. Stan Cooper
Hoveround Corporation
2151 Whitfield Industrial Way
Sarasota, Florida 34243

Re: K991132
Trade Name: Activa
Regulatory Class: II
Product Code: INI
Dated: July 22, 1999
Received: July 23, 1999

Dear Mr. Cooper:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991132

Device Name: ACTIVA

Indications For Use: TO PROVIDE FOR THE CONSUMING PUBLIC, A SELF-CONTAINED, COMPACT PERSONAL MOBILITY VEHICLE FOR PERSONS WHO ARE UNABLE TO AMBULATE EITHER BECAUSE OF MEDICAL NECESSITY OR THROUGH PERSONAL PREFERENCE THE ~~VEHICLE~~ SEE VEHICLE IS OPERABLE BOTH INDOORS AND OU BUT PRIMARILY INTENDED FOR OUTDOOR USAGE.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices K991132
510(k) Number

Prescription Use____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)