NOV 6 1998

# JUPITER 50F SCOOTER 510(k) SUMMARY

## SUMMARY OF SAFETY AND EFFECTIVENESS K983407

### ACEME Technologies International

**1. This 510(k) Summary is submitted, in conjunction with a full submission, this 22nd day of September, 1998, by:**


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Vice President & Research Director


Date Prepared: September 22, 1998

**2. Device**

Device Name: Jupiter 50F Scooters

Generic Name: Motorized 3-wheeled Scooter

Classification: Class II

Product Code: 89INI

Regulation Number: 890.3800

**3. Predicate Device on Which We Base Equivalence**

Pride Health Care Legend Scooter
510(k) number -- K926295
Product Code -- 89INI

**4. Description of Device**

The Jupiter 50F electric scooter is a mobility assistive device for physically challenged people and elderly people. It is motorized by a 24V DC motor. Two or four 12 volt batteries supply electrical power.

Jupiter 50F consists of seven major components: chassis, body covers, transaxle, seat, controller, batteries, and battery charger.

The chassis is divided into three parts: the tiller, the front and the rear chassis. The front and rear chassis are jointed by two pin shafts and secured by two U-shaped pins. They can be assembled or dismantled in less than a minute without using any tools. The tiller is articulated by its upper and lower parts to provide the maximum flexibility. There is a wind shield attached to the handle bar. A unique function of this is to provide a temporary table for holding coffee cup, books, and et. A Jupiter's user can write or work with convenience.

The scooter fairing are made of high-strength plastic - PBS. They cover the chassis and tiller. Their surfaces are painted by baked paint with high finishing. A headlight is installed in the front fairing and two turning lights are in the rear. Those lights enhance drive safety greatly by providing not only signals to other vehicle drivers and pedestrians, but also by lighting road surface and obstacles to avoid collision or other accidents.

A sealed drive train is used in Jupiter scooter. No moving part is exposed. A 24-volt permanent magnetic direct current motor delivers up to 400 Watts power to the system. Motor speed is reduced through gear pairs to its desired wheel shaft speed. The inbedded differential gives the right and the left wheel different speed when the scooter makes turn. All moving parts and bearings inside the gear box are well lubricated by low-viscosity grease. The design of every part is carefully calculated and tested. Such design reduces requirement in maintenance and greatly increases its reliability and ensure a long service life.

An electric dynamic brake is attached to the motor shaft. The braking function is applied when no electric current passes its inductive coils and vanishes when speed control throttle is activated. The Jupiter can stay firmly on a slope of 9 degrees without slipping. This is a very important safety feature every scooter must have in case of sudden electric circuit failure. There is a clutch handle to release the brake locking in order to free wheeling when needed.

Two 30 Ah 12-Volt sealed gel-cell batteries are secured at the top of chassis. A full charge can make a 25 miles travel. The Jupiter 50F also can accommodate four batteries. It increases travel distance to more than 40 miles, and lowers the center of gravity of the man-vehicle system, therefore it improves its static and dynamic stability substantially.

The battery charger is built-in with a extension cord. A user can charge the batteries conveniently wherever a power outlet can be found. It takes 6 to 8 hours to charge an almost discharged battery pack back to full capacity. In an unexpected power-off event, a couple of hours charging may get enough battery energy to allow the user to drive home.

The speed of the Jupiter scooter is controlled by two potentiometers. One is used to set up its maximum speed, and the other used to vary speed from zero to its specified maximum. The maximum possible speed is 5.0 miles per hour. The Jupiter 50F uses a Curtis controller that is widely used in powered wheelchairs and scooters all over the world, including the Shopriders.

The Jupiter 50F is a derivative from its predecessor, Jupiter 50, which is a three-wheeled scooter. The Jupiter 50 has the same aforementioned driving power train, rear chassis, electronic control system, electrical wiring system, seating, tiller, rear fairing, and wheels, except the number of front wheels and its steering mechanism.

The four-wheeled design increases the supporting area on ground surface and the swign-arm design for the wheels reduces its maximum turning angle from 90° to 31°. The Jupiter 50F users may not be able to make a sharp turning so that tip-over accidents will be greatly lessened. Our 4-wheeled Jupiter 50F did not show tip-over during its performance test and is much more stable and safer than 3-wheelers.

The Jupiter 50F is intended to be used by the physically challenged and active elderly people as a mobility assistive device. It enhance user's mobility. People who can walk but not strong enough to endue even a short distance or simply use it for convenience will find that the Jupiter scooters are ideal for them.

**5. Similarities and Differences to Predicate Device**

Our study has demonstrated that the Jupiter is substantially equivalent to the Legend 4-wheeled scooters.

**(1). Similarities**

The similarities between the Jupiter and the Legend can be identified from their appearances and performances. In principle, both scooters cab be used either indoors and outdoors, and the intended users are the physically challenged people and elderly people. The features built in the Jupiter may be easily found in those Legend.

(a). Both the Jupiter and Legend are intended to be used by physically challenged people and elderly people.

(b). Both can be used indoors and outdoors.

(c). The Jupiter 50F and Legend scooters both use a 24 volt DC permanent magnetic motor with sealed transaxle drive unit.

(d). Both use a disk-type coil-activated electric brake.

(e). The motor control boards are the same with respect to the power FET design.

(f). True regenerative and dynamic braking provide complete downhill and deceleration speed control in both scooters.

(g). Each has an industrial-typical wig-wag potentiometer, forward/reverse speed control, along with a speed limit potentiometer.

(h). The maximum forward speeds in both scooters are in the limit of 6 miles per hour specified by ANSI/RESNA.

(i). The maximum reverse speeds in both scooters are designed to be 60% of the their maximum forward speeds, respectively.

(j). Speeds of both scooters can be controlled from zero to their maximum

(k). Both scooters feature upholstered seats with removable armrests and height adjustment capability. Seats on each swivel 360 degrees.

(l). All major dimensions are similar.

(m). Each uses two 12-volt U-1 type batteries as their power source, and each uses commercially available built-in battery charger.

(n). The console on each has a battery indicator, horn switch or button, power switch, and speed limit potentiometer.

(o). The range of each is almost the same.

**(2). Differences**

There are some differences between the Jupiter and the Legend. Those differences neither are substantial, nor cause any safety concerns. As matter of fact, the Jupiter have been improved by introduced some features, such as head light and turning lights, four battery option, and bigger front wheels.

| | **Jupiter 50F** | **Legend** |
|---|---|---|
| Wheels | all 10" tires | two 9"/two 10" |
| Battery | optional 4 batteries | no option |
| Lights | Front light<br>Rear signal lights | no<br>no |
| Windshield/table | yes | no |
| Seat Post | Gas-filled cylinder for auto height adjustment and cushioned ride | no |

To summarize the similarities and differences, Table 1 tabulates some important structure and performance data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 1998

Tong Zhou, Ph.D.
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Sacramento, California 95820

Re: K983405
Trade Name: ACEME Jupiter Scooter, Motorized 3-Wheeled Jupiter 50
K983407
Trade Name: ACEME Jupiter Scooter, 4-Wheeled Jupiter 50F
Regulatory Class: II
Product Code: INI
Dated: September 23, 1998
Received: September 28, 1998

Dear Dr. Zhou:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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

Enclosures

## II. Indication for Use Statement

510(k) Number (if known). K 983407

Device Name: Jupiter 50F Motorized 4-Wheeled Vehicle

**Indications for Use**

Used as an indoor and outdoor mobility assistive device. Never used as a transportation tool on highways and freeways

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983407

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