DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 9, 2016

Solar Mobility LLC
% E.J Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K153636
Trade/Device Name: Liberator Powered Wheelchair with Solar Companion
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: August 9, 2016
Received: August 9, 2016

Dear E.J Smith:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153636

Device Name
Liberator Powered Wheelchair with Solar Companion

Indications for Use *(Describe)*
The intended use of the Liberator™ is to provide mobility for those persons limited to a seated position, which are capable of operating a simple hand control.

The Liberator™ may be operated on internal DC batteries, which can be recharged by using a wall- charger and supplemented by using the detachable solar assisted battery maintaining device (Solar Companion).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Sponsor:

Company Name:	Solar Mobility LLC
Address:	1426 East 3rd Avenue Suite B110
	Kennewick, WA 99336
Telephone:	509.851.3611
Contact Person:	Kurt Schneider

Summary Preparation Date: **August 28, 2016**

Device Name

Trade Name:	Liberator Powered Wheelchair with Solar Companion
Common Usual Name:	Powered Wheelchair
Classification Name:	Powered Wheelchair
Product Code(s):	ITI
Regulation Number:	21 CFR 890.3860
Device Class:	Class II
Panel:	Office of Device Evaluation (ODE) Division of Neurological and Physical Medicine Devices

Predicate Device:

Manufacturer	Brand Name	510(k) Number
Golden Technologies, Inc.	Golden Spyder	K041341
Aspetic International	AFU-14CF Expedition Dental System	K050201

Device Description:

The *Liberator™* powered wheelchair is a six wheeled battery powered wheelchair. It has a controller system, which is used to operate the *Liberator™* powered wheelchair. The one-piece base of the wheelchair is made of welded steel construction. The main frame also consists of a battery floor pan. The center drive wheels are mounted on the drive shafts of separate motor/gear assemblies, one on the left side of the wheelchair, the other on the right side of the wheelchair. The seat comes with ergonomic contoured comfort cushions, recliner, tilt-up adjustable arm rests, and patient can dial in their seating

Position, can adjust the setting for air fan control, joy stick adjustments and table adjustments and settings. The *Liberator*™ powered wheelchair requires 2 NF22 batteries, has an on board charger, the Solar Companion, with solar panel and an assisted battery maintaining device (Solar Companion).

The *Liberator*™ powered wheelchair has a maximum load capacity of 300 lbs.

The *Liberator*™ can travel at ranges of 15-20 miles with maximum speed of 4.09 miles per hour on flat terrain under ideal conditions (RESNA testing). In order to achieve the maximum extended range of 20 miles the Solar Companion has the ability to maintain the batteries based on the intensity, angle, and availability of sunlight.

The *Liberator*™ has an air ride suspension system seat, cushion ventilation system (fan) for the seat and lumbar cushion with laser ported holes in fabric.

The Solar Companion is an onboard battery maintaining device that comes with the *Liberator*™. It has the ability to maintain the batteries based on availability sunlight intensity and angle. The solar panel assembly is affixed to the *Liberator*™ and the height can be adjusted to allow the user excellent visibility

Indications for Use

The intended use of the *Liberator*™ is to provide mobility for those persons limited to a seated position, which are capable of operating a simple hand control.

The *Liberator*™ may be operated on internal DC batteries, which can be recharged by using a wall-charger and supplemented by using the detachable solar assisted battery maintaining device (Solar Companion).

Technological Characteristics Discussion

The *Liberator*™ powered wheelchair and the predicate have identical frame material, overall length and width, maximum speed, turning radius, controller, battery type, AC-Wall Charger, suspension system, drive wheels, casters, footplate, footplate adjustable heights, armrest type, seat size depth, and wheel locks.

The *Liberator*™ powered wheelchair has similar seat size widths and heights, back adjustment angle, armrest heights, and upholstery material.

The *Liberator*™ powered wheelchair has a battery maintaining device (Solar Companion) which is not offered on the predicate device. The Solar Companion safety was established by conducting EMC testing and effectiveness was determined through RESNA testing.

The *Liberator*™ Powered Wheelchair incorporates a seat cushion which allows the user to have an air ride suspension system which reduces the amount of jarring, friction and shear factor associated with a normal wheelchair seat and allows for a smoother ride for the patient. The predicate device offers a standard wheelchair cushion. The differences between the two seat cushions raises no new safety issues. This conclusion was reached after the *Liberator*™ powered wheelchair passed the required RESNA tests.

The *Liberator*™ powered wheelchair and the predicate have a maximum load capacity of 300 lbs.

The *Liberator*™ powered wheelchair has a range per charge of approximately 15-20 miles based on RENSA Testing Section 4 Determination of Energy Consumption Theoretical Range. The predicate device advertises a theoretical range of 15 miles. The RESNA testing for the Liberator™ supports a theoretical range of 15-20 miles per charge.

The Liberator™ Powered Wheelchair and predicate have a wheelchair weight and overall height difference due to the fact the Liberator Powered Wheelchair has the Solar Companion onboard battery maintaining device and Solar Companion frame attached to the wheelchair. RESNA testing was conducted with the Solar Companion accessory attached to the wheelchair to ensure the Solar Companion accessory did not have any unintended impact on the performance of the wheelchair. RESNA testing supports the safe use of the *Liberator*™ with the Solar Companion.

The indications for use for the AEU-14CF Expedition Emergency Field Dental Unit differ from the *Liberator*™ Powered Wheelchair in their intended use. However, both offer the user the capability of prolonging the life of the batteries (while in use) using a solar panel as a source of energy for onboard battery maintenance. Both the subject device and the predicate offer a detachable solar panel.

Non-Clinical Testing

- RESNA WC-1 Volume Requirements and Test Methods for Wheelchairs (including Scooters) Section 1 Determination of static stability
- RESNA WC-2 Volume 2American National Standard for Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 2: Determination of dynamic stability of electrically powered wheelchairs
- RESNA WC-2 Volume 3 Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 3: Determination of effectiveness of brakes
- RESNA WC-2 Volume 2 Section 4: Energy consumption of electrically powered wheelchairs and scooters for determination of theoretical distance
- RESNA WC-1 Volume 1 Requirements and Test Methods for Wheelchairs (including Scooters) Section 5: Determination of dimensions, mass and maneuvering space
- RESNA WC-2 Volume 2 Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 6: Determination of maximum speed,
- RESNA WC-1 Volume 1 Requirements and Test Methods for Wheelchairs (including Scooters) Section 7: Method of Measurement of Seating and Wheel Dimensions
- RESNA WC-2 Volume 1 Requirements and Test Methods for Wheelchairs (including Scooters) Section 8: Requirements and test methods for static, impact and fatigue strengths
- RESNA WC-2 Volume 2 Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 9: Climatic tests for electrically powered wheelchairs
- RESNA WC-2 Volume 2 Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
- RESNA WC-1 Volume 1 Requirements and Test Methods for Wheelchairs (including Scooters) Section 11: Test dummies

- RESNA WC-1 Volume 1 Requirements and Test Methods for Wheelchairs (including Scooters) Section 13: Determination of coefficient of friction of test surfaces
- RESNA WC-2 Volume 2 Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 14: Power and control systems for electrically powered wheelchairs, Requirements and test methods
- RESNA WC-1 Volume 1 Requirements and Test Methods for Wheelchairs (including Scooters) Section 15: Requirements for information disclosure, documentation and labeling
- RESNA WC-1 Volume 1 Requirements and Test Methods for Wheelchairs (including Scooters) Section 16: Resistance to ignition of upholstered parts - Requirements and test methods
- RESNA WC-2 Volume 2 Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters
- RESNA WC-1 Volume 1 Requirements and Test Methods for Wheels chairs (including Scooters) Section 22: Set-up procedures
- RESNA WC-1 Volume 1 Requirements and Test Methods for Wheelchairs (including Scooters) Section 26: Vocabulary
- ISO 7176-21: 2009 Requirements and Test Methods for Electromagnetic Compatibility of Electric Powered Wheelchairs and Motorized Scooters: Solar Companion onboard battery maintaining device

Clinical Testing

No clinical studies were conducted.

Conclusion

The *Liberator™* powered wheelchair has the same intended use and similar technological characteristics as the Golden Spyder. Non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety and effectiveness. Thus, the *Liberator*™ powered wheelchair device is substantially equivalent to the predicate device.