



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 12, 2016

Whill, Inc.
% Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K153543
Trade/Device Name: Whill Model M
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: January 28, 2016
Received: January 29, 2016

Dear Mark Job:

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

Indications for Use

510(k) Number (if known)

K153543

Device Name

WHILL Model M

Indications for Use (Describe)

The intended use of the Model M powered wheelchair is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

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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5 510(k) Summary

Submitter's Name:	WHILL, Inc.
Address:	285 Old County Rd, Suite 6, San Carlos CA
Contact Person:	Terese Bogucki
Title:	Regulatory Consultant
Telephone Number:	650-488-7799
Fax Number:	650-227-2264
Email:	terri@decusbiomedical.com
Date Summary Prepared:	August 24, 2015
Device Proprietary Name:	WHILL Model M Powered Wheelchair
Model Number:	Model M
Common Name:	Powered Wheelchair
Regulation Number:	21 CFR 890.3860
Product Code:	ITI
Device Class:	II

Predicate Device

Trade Device Name:	F3 Corpus
Manufacturer:	Permobil AB
Address:	Per Uddens Vag 20 Timra, SE 86123 Vasternorrland Sweden
Regulation Number:	21 CFR 890.3860
Regulation Name:	Wheelchair, Powered
Regulatory Class:	Class II
Product Code:	ITI
510(k) Number:	143180
510(k) Clearance Date:	March 27, 2015

5.1 Description of the Device

The WHILL Model M is an indoor/outdoor battery-operated 4 wheel drive powered wheelchair. It is powered by two 12 VDC 50Ah batteries and controlled by the R-net 120 amp motor controller. As with all commercially-available powered wheelchairs, the user sits in the wheelchair seat and uses controls positioned on the arms to turn the chair on, control the speed, and direct the movement. The directional controller can be mounted on the left or right arm. When the user activates the directional controller the brakes are released and the motors rotate to move the device in the desired direction. When the user releases the directional controller the device is brought to a controlled stop.

The chair frame is a welded nut and steel construction and includes two rear wheels with drive units (motor, gear and brake) connected by belts to the front all directional wheels. Adjustments can be made to the two arm supports, foot support, and seat height and depth to position the user correctly in the device. The device supports a maximum weight of 220 lb, and has an approximate driving range of 12 miles. The device can be operated on carpet, tile, wood, vinyl, concrete, blacktop, dirt, gravel, grass, and wet (<1” standing water) surfaces.

5.2 Indications for Use

The intended use of the Model M powered wheelchair is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

5.3 Summary of Technological Characteristics Comparison

Table 5-1 shows the similarities and differences between the two products. The key difference is that the subject device has the front all-directional wheel and the device controls on two arms instead of one. While these characteristics are different, the testing demonstrates that they do not raise new questions of safety or effectiveness.

Table 5-1 Summary of Technological Characteristics Comparison

Item	Predicate	Subject Device
General		
Manufacturer	Permobil AB	WHILL, Inc.
Model	F3 Corpus	Model M
510(k) Number	K143180	unknown

Item	Predicate	Subject Device
Intended Use	To provide indoor and outdoor mobility to persons restricted to a sitting position that are capable of operating a powered wheelchair.	Same
Indications for Use	The intended use of the F3 powered wheelchair is to provide indoor and outdoor mobility to persons limited to a seating position that are capable of operating a powered wheelchair.	The intended use of the Model M powered wheelchair is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.
Rx/OTC Designation	Rx or OTC	Rx
Physical Characteristics		
Device Width	24"	23.6"
Device Length	Drive base only: 40" with anti-tippers 36" without anti-tippers	37"- 42" (depending on foot plate setting)
Weight (including batteries)	386 lb with Group 34 batteries 405 lb with Group 24 batteries	240 lb
Device Construction	Steel	Welded nut and steel
Batteries (2)	12VDC 60Ah (Group M34) or 12VDC 73Ah (Group M24)	12V 50Ah
Operating Characteristics		
Maximum Weight Capacity	300 lb (136 kg)	220lb (100kg)
Maximum Speed	6 mph 5 mph (without anti-tippers)	5.5 mph
Turning Radius	26.5"	28"
Obstacle Climbing Height	3"	3"
Drive System	Front wheel drive	4 Wheel Drive
Dynamic Stability (incline)	6 degrees	10 degrees

Item	Predicate	Subject Device
Driving Range (full battery charge)	13 miles	12 miles
Battery Charging Time	8 hours	~8 hours to 80%
Design Features		
Power Controller	R-net 120 amp controller	R-net 120 amp controller
Speed Settings	5 (maximum)	3
Front Wheel Type	Pneumatic or foam-filled	All directional wheel
Rear Wheel Type	Solid polyurethane	Pneumatic or solid
Anti-tip Wheels	Front anti-tip wheels (optional)	Rear anti-tip wheels
Pressure relief handles	None	Yes
Seat slide	No	Yes
Tail lamps (2)	Reflectors Lights (optional)	Red LED lights (always on)
Chair Tilt/ Recline/ Leg Lift/ Seat Elevator	Yes	No
Tie Downs	Yes	Yes (optional)
Non-Clinical Performance Testing		
Wheel Performance Testing	Detailed performance testing conducted to ISO 7176 standard	Detailed performance testing conducted to RESNA WC-1, WC-2 and WC-4 standards
Flammability	Padded parts: EN 1021-1, EN 1021-2 and ISO 7176-16 Plastic parts: UL94	Upholstered parts: ISO 8191-1 and ISO 8191-2 and covers: ISO 7176-16 Plastic parts: UL94

5.4 Performance Data

In addition to design verification and validation testing WHILL conducted performance testing to demonstrate the subject device is in compliance with the following test standards:

- ANSI/RESNA WC-1:2009 Section 1: Determination of Static Stability
- ANSI/RESNA WC-2:2009 Section 2: Determination of Dynamic Stability
- ANSI/RESNA WC-2:2009 Section 3: Determination of Effectiveness of Brakes
- ANSI/RESNA WC-2:2009 Section 4: Determination of Static Stability Determination of Dynamic Stability Determination of Effectiveness of Brakes Energy Consumption for Determination of Theoretical Distance
- ANSI/RESNA WC-1:2009 Section 5: Maneuvering Space Determination of Dimensions, Mass and Maneuvering Space
- ANSI/RESNA WC-2:2009 Section 6: Determination of Maximum Speed, Acceleration and Deceleration
- ANSI/RESNA WC-1:2009 Section 7: Method of Measurement of Seating and Wheel Dimensions
- ANSI/RESNA WC-1:2009 Section 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths
- ANSI/RESNA WC-2:2009 Section 9: Climatic Tests
- ANSI/RESNA WC-2:2009 Section 10: Determination of Obstacle Climbing
- ANSI/RESNA WC-1:2009 Section 11: Test Dummies
- ANSI/RESNA WC-1:2009 Section 13: Determination Of Coefficient Of Friction Of Test Surfaces
- ANSI/RESNA WC-2:2009 Section 14: Power And Control Systems For Electrically Powered Wheelchairs - Requirements And Test Methods
- ANSI/RESNA WC-1:2009 Section 15: Requirements for Information Disclosure, Documentation and Labeling
- ANSI/RESNA WC-1:2009 Section 16: Resistance to ignition of upholstered parts - Requirements and test methods (tests to ISO 8191-1 and ISO 8191-2)
- ANSI/RESNA WC-4:2012 Section 19: Wheelchairs used as seats in motor vehicles
- ANSI/RESNA WC-2:2009 Section 21: Requirements and Test Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Motorized Scooters

- ASTM D4169, Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 7176-16: 2012 Wheelchairs -- Part 16: Resistance to ignition of postural support devices
- ISO 8191-1: 1987 Furniture -- Assessment of the ignitability of upholstered furniture -- Part 1: Ignition source: smouldering cigarette
- ISO 8191-2: 1988 Furniture -- Assessment of ignitability of upholstered furniture -- Part 2: Ignition source: match-flame equivalent
- UL 94 Standard for Tests for Flammability of Plastic Materials for Parts in Devices and Appliances
- ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- ISO 7176-14: 2008 Wheelchairs -- Part 14: Power and control systems for electrically powered wheelchairs and scooters -- Requirements and test methods (for R-Net Power Module)

Based upon the results of this testing, it was determined the Model M performance was substantially equivalent to the predicate device.

5.5 *Substantial Equivalence Conclusion*

The July 28, 2014 FDA Guidance entitled “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]” was used to determine substantial equivalence. The analysis shows that the Intended Use and Indications for Use, principles of operation, and conditions of use are identical, and that differences in technical characteristics do not raise different questions of safety and effectiveness. There are technological differences between the subject and predicate device however, the results of performance testing demonstrate that these differences do not raise any new questions of safety or effectiveness compared to other similar powered wheelchairs currently on the market. Therefore one can conclude that the Model M is substantially equivalent to the predicate Permobil F3 Corpus device.