November 9, 2021

Whill, Inc.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K213383
Trade/Device Name: WHILL Model C2
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: October 12, 2021
Received: October 13, 2021

Dear Prithul Bom:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213383

Device Name
WHILL Model C2

Indications for Use *(Describe)*
The intended use of the WHILL Model C2 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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510(k) SUMMARY: K213383

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Whill, Inc.
2-1-11 Higashi-Shinagawa; Harbor Premium Building 2F
Shinagawa-ku, Tokyo 140-0002 Japan
Phone: +819025672984
Contact Person: Tsuyoshi Iriyama
Date Prepared: July 15, 2021

II. DEVICE

Name of Device:	WHILL Model C2
Classification Name:	Physical Medicine
Regulation:	21 CFR § 890.3860
Regulatory Class:	Class II
Product Classification Code:	ITI

III. PREDICATE DEVICE

Primary Predicate Device

- Manufacturer: Whill, Inc.
- Trade Name: WHILL Model M
- 510(k): K153543
- Classification Name: Physical Medicine
- Regulation: 21 CFR § 890.3860
- Regulatory Class: Class II
- Product Classification Code: ITI

IV. REFERENCE DEVICES

Reference Device 1

- Manufacturer: Dongguan Prestige Sporting Goods Co., Ltd
- Trade Name: Solax Powered Wheelchair
- 510(k): K182576
- Classification Name: Physical Medicine
- Regulation: 21 CFR § 890.3860
- Regulatory Class: Class II
- Product Classification Code: ITI

Reference Device 2

- Manufacturer: Alber GmbH
- Trade Name: e-motion M25
- 510(k): K192618
- Classification Name: Physical Medicine
- Regulation: 21 CFR § 890.3860
- Regulatory Class: Class II
- Product Classification Code: ITI

V. DEVICE DESCRIPTION

The subject device is an update to the existing previously cleared WHILL Model M (K153543). The WHILL Model C2 is an indoor/outdoor battery-operated 2-wheel drive (rear-wheel drive) powered wheelchair. It consists of four parts: seat system, control system, braking system, and drive system. It consists of two motors drive systems, an electromagnetic braking system, an electric motor controller, and a lithium-ion battery with an off-board battery charger. The wheelchair is powered by a 25.3V DC 10.6A rechargeable lithium-ion battery charged by an off-board lithium-ion battery charger.

The control system, including the directional controller (joystick), is equipped on the control pad that attaches to the armrest. When the joystick is released, the electromagnetic brakes will be actuated, and the power wheelchair is slowed to a stop.

As with all commercially available powered wheelchairs, the user sits in the wheelchair seat and uses the control system such as the control pad positioned on either of the two arms to turn the chair on, control the speed, and direct the movement. Adjustments can be made to the seating to fit the user's body. Like the predicate device WHILL Model M, the two side-arms can be rotated out of the way to make it easier for the user to get into and out of the device.

Model C2 also contains Bluetooth-based RF wireless technology. The wireless technology is identical to the legally marketed reference device 2, e-motion-M25 (K192618). The device can be controlled by the directional controller or remote control by a smartphone app via Bluetooth Low Energy (BLE) wireless communication interface. The smartphone app is used to drive the chair remotely. (Note: For safety, Joystick control is priority over the remote control by design.) The smartphone app can also view the battery's status, adjust the speed and acceleration setting and lock the unattended device. The user can lock and unlock the device remotely via the BLE interface using the smartphone app or using a smart key fob.

The device supports a maximum weight of 136Kg (300lbs.), including the weight of the occupant and any carried items. It has a maximum driving range of 11miles (18km) with a maximum speed limit of up to 5mph (8km/h).

VI. INDICATIONS FOR USE

The intended use of the WHILL Model C2 powered wheelchair is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PRIMARY PREDICATE DEVICE

The indications for use, design, and function of the subject device are identical to the primary predicate device WHILL Model M (K153543). The following characteristics were compared between the subject device and the predicate devices to demonstrate substantial equivalence:

- ***Indications for Use:*** WHILL Model C2 has the same indications of use, principles of operation, and similar technical characteristics as the previously cleared primary predicate device, WHILL Model M (K153543). Both are indicated for indoor and outdoor mobility to persons limited to a seated position capable of operating a powered wheelchair.

- ***Materials:*** The subject device has more surface contacting components than the primary predicate device, and the subject device's surface-contacting parts are tested to *ISO 10993* standard.
- ***Design***: The subject device uses the same technology as the primary predicate device. The key differences are that the subject device is a rear-wheel drive, uses Brushless DC motors over brushed DC motors to achieve lightweight and portability, uses WHILL Motor controller over R-Net power module, and the device controls are on one arm instead of two. These features have been safety and performance-tested to ISO 7176 standard. The testing demonstrates that the differences do not raise new questions of safety or effectiveness.
- ***Energy Source:*** The subject device and the primary predicate are both powered by batteries. The key difference is that the subject device uses a Lithium-ion battery over lead-acid batteries for compatibility with the brushless DC motors. The Lithium-ion battery used in the subject device has been safety tested to *IEC 62133-2* standard.
- ***Performance Testing:*** Both the predicate and subject devices were subjected to the same biocompatibility and performance tests listed below in ***Section-X***

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE REFERENCE DEVICE 1

The subject device is for Over-the-Counter use. Hence Solax Powered Wheelchair- S7102 (K182576) is chosen as the reference device 1 to account for the OTC indication.

- ***Indications for Use:*** WHILL Model C2 has similar indications of use, principles of operation, and similar technical characteristics as the reference device 1, Solax Powered Wheelchair (K182576). Although there is a minor difference in the indications of use, the primary indication of both the subject device and the reference device 1 is to assist with mobility to users limited to a seated position who can operate and control the powered wheelchair.
- ***Materials:*** The subject device has more surface contacting components tested to ISO 10993 standard. There is no mention of the surface contacting components and biocompatibility test for reference device 1 in the 510(k) summary
- ***Energy Source:*** The subject device and the reference device 1 are both powered by a Lithium-ion battery. The Lithium-ion battery used in the subject device has been safety tested to *IEC 62133-2* standard.
- ***Performance Testing:*** Both the reference device 1 and subject devices were subjected to the same performance tests listed below in ***Section-X***

IX. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE REFERENCE DEVICE 2

The subject device includes an additional feature of Radio Frequency wireless technology. To account for the additional feature, e-motion-M25(K192618) is chosen as the reference device 2. The RF wireless technology and standards are identical to the reference device 2. The following characteristics and standards were compared between the subject device and the reference device 2:

- ***Wireless functionality***: The subject device and the reference device 2 have similar wireless functionality of controlling the device with a smartphone app (iOS, Android) via Bluetooth Low Energy.
- ***Wireless RF frequency range***: Both the primary and reference device 2 have an identical

Wireless RF frequency range.

- ***Wireless operating range:*** Both the primary and reference device 2 have an identical operating range.
- ***Wireless testing:*** Both the reference device 2 and subject devices were subjected to the same FCC Radio Frequency Testing and wireless co-existence testing listed below in *Section-X*

X. SAFETY AND PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination. (*Table 1 Table 2 Table 3*)

Sterilization & Shelf-life Testing

The device is provided non-sterile and is used non-sterile. There are no parts that can expire, and thus, there is no shelf life.

Non-clinical performance testing:

The subject device, primary predicate, reference device 1, and the reference device 2 were tested to the ISO 7176 standard, while the primary predicate device was tested to the RESNA WC-1 and WC-2 standard. Both standards are listed as acceptable per the FDA document entitled *"Guidance Document for the Preparation of Premarket Notification [510k)] Applications for Mechanical and Powered Wheelchairs and Motorized Three-Wheeled Vehicles."*

Table 1 Comparison of Non-Clinical Testing WHILL Model C2 with predicate device and reference devices.

Subject Device WHILL Model C2	Primary Predicate Device WHILL Model M (K153543)	Reference Device 1 Solax Powered Wheelchair (K182576)	Reference Device 2 e-motion M25 (K192618)
ISO 7176-1 Third edition 2014-10-01 Wheelchairs - Part 1: Determination of static stability	American National Standard for Wheelchairs - RESNA Volume 1: Requirements and Test Methods for Wheelchairs (Including Scooters) Section 1 Determination of Static Stability	ISO 7176-1: 2014, Wheelchairs - Part 1: Determination of static stability	ISO 7176-1 Wheelchairs – Part 1: Determination of static stability
ISO 7176-2 Third edition 2017-10 Wheelchairs - Part 2:Determination of dynamic stability of electrically powered wheelchairs	American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (Including Scooters) With Electrical Systems Section 2: Determination of Dynamic Stability of Electrically Powered Wheelchairs	ISO 7176-2 Wheelchairs – Part 2: Determination of dynamic stability of electric wheelchairs	ISO 7176-2 Wheelchairs – Part 2: Determination of dynamic stability of electric wheelchairs
ISO 7176-3 Third edition 2012-12-15 Wheelchairs - Part 3: Determination of effectiveness of brakes	American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (Including Scooters) With Electrical Systems Section 3: Determination of Effectiveness of Brakes	ISO 7176-3: 2012, Wheelchairs - Part 3: Determination of effectiveness of brakes	ISO 7176-3 Wheelchairs – Part 3: Determination of efficiency of brakes
ISO 7176-4 Third edition 2008-10-01Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range	American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (Including Scooters) With Electrical Systems Section 4: Energy Consumption of Electrically Powered Wheelchairs and Scooters for Determination of Theoretical Dis	ISO 7176-4, Third edition 2008-10-01, Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range	ISO 7176-4 Wheelchairs – Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
ISO 7176-5 Second edition 2008-06-01Wheelchairs - Part 5: Determination of overall dimensions, mass and maneuvering space	American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (Including Scooters) Section 5: Determination of Dimensions, Mass and Maneuvering Space	ISO 7176-5, Second edition 2008-06-01, Wheelchairs - Part 5: Determination of overall dimensions, mass and maneuvering space	ISO 7176-5 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space

Subject Device WHILL Model C2	Primary Predicate Device WHILL Model M (K153543)	Reference Device 1 Solax Powered Wheelchair (K182576)	Reference Device 2 e-motion M25 (K192618)
ISO 7176-6 Third edition 2018-06 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs	American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (Including Scooters) With Electrical Systems Section 6: Determination of Maximum Speed, Acceleration and Deceleration of Electrically Powered Wheelchairs	ISO 7176-6: 2001, Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of Powered Wheelchairs	ISO 7176-6 Wheelchairs – Part 6: Determination of maximum speed, acceleration, and deceleration of electric wheelchairs
ISO 7176-8 Second edition 2014-12-15 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths	American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (Including Scooters) Section 8: Requirements and Test Methods for Static, Impact And Fatigue Strengths	ISO 7176-8:2014, Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths	ISO 7176-8 Wheelchairs – Part 8: Requirements and test methods for static, impact, and fatigue strengths
ISO 7176-9 Third edition 2009-11-15Wheelchairs - Part 9: Climatic tests for electric wheelchairs	American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (Including Scooters) Section 9: Climatic Tests for Electrically Powered Wheelchairs	ISO 7176-9:2009, Wheelchairs - Part 9: Climatic tests for Powered Wheelchairs	ISO 7176-9 Wheelchairs – Part 9: Climatic tests for electric wheelchairs
ISO 7176-10 Second edition 2008-11 01Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs	American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (Including Scooters) With Electrical Systems Section 10: Determination of Obstacle-Climbing Ability of Electrically Powered Wheelchairs	ISO 7176-10:2008, Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs	ISO 7176-10 Wheelchairs – Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
ISO 7176-11 Second edition 2012-12-01Wheelchairs - Part 11: Test dummies	American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (Including Scooters) Section 11: Test Dummies	ISO 7176-11, Second edition 2012-12-01, Wheelchairs - Part 11: Test dummies	ISO 7176-11 Wheelchairs – Part 11: Test Dummies

Subject Device WHILL Model C2	Primary Predicate Device WHILL Model M (K153543)	Reference Device 1 Solax Powered Wheelchair (K182576)	Reference Device 2 e-motion M25 (K192618)
ISO 7176-13: 1989 Wheelchairs - Part 13: Determination of Coefficient of Friction of Test Surfaces	American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (Including Scooters) Section 13: Determination of Coefficient of Friction of Test Surfaces	ISO 7176-13, First edition 1989-08-01, Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces	ISO 7176-13: 1989 Wheelchairs - Part 13: Determination of Coefficient of Friction of Test Surfaces
ISO 7176-14 Second edition 2008-02-15 Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods	American National Standard for Wheelchairs - 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	ISO 7176-14:2008, Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods	ISO 7176-14 Wheelchairs – Part 14: Power and control systems for electrically powered wheelchairs and scooters. Requirements and test methods
ISO 7176-15 First edition 1996-11-15 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling	American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (Including Scooters) Section 15: Requirements for information disclosure, documentation, and labeling	ISO 7176-15:1996, Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling	ISO 7176-15 Wheelchairs – Part 15: Requirements for information disclosure, documentation, and labeling

Subject Device WHILL Model C2	Primary Predicate Device WHILL Model M (K153543)	Reference Device 1 Solax Powered Wheelchair (K182576)	Reference Device 2 e-motion M25 (K192618)
ISO 7176-16 Wheelchairs – Part 16: Resistance to ignition of postural support devices- ISO 8191-2:1988 Furniture — Assessment of ignitability of upholstered furniture — Part 2: Ignition source: match-flame equivalent	Cushions used are purchased components that are FDA-listed and compliant with ISO 8191-1 and ISO 8191-2, covers are compliant with ISO 7176-16	ISO 7176-16, Second edition 2012-12-01, Wheelchairs - Part 16: Resistance to ignition of postural support devices	ISO 7176-16 Wheelchairs – Part 16: Resistance to ignition of postural support devices
ISO 7176-21 Second edition 2009-04-01Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers	American National Standard for Wheelchairs - 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	ISO 7176-21 Second edition 2009-04-01 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers	-ISO 7176-21 Wheelchairs – Part 21: Requirements and test methods for electromagnetic compatibility
ISO 7176-22 Second edition 2014-09-01 Wheelchairs - Part 22: Set-up procedure	ANSI RESNA WC-1:2019 Section 22 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheels chairs (including Scooters) Section 22: Set-up Procedures	ISO 7176-22 Second edition 2014-09-01 Wheelchairs - Part 22: Set-up procedures	Not Mentioned
UN 38.3 Recommendations of the TRANSPORT OF DANGEROUS GOODS, Manual of Test and Criteria, Part III, Lithium metal and lithium-ion batteries	NA	NA	UN 38.3 Recommendations of the TRANSPORT OF DANGEROUS GOODS, Manual of Test and Criteria, Part III, Lithium metal and lithium-ion batteries

Biocompatibility Testing

Biocompatibility assessment of patient-contacting components in the subject device was performed in conformance with *iso 10993-1, "biological evaluation of medical devices - part 1: evaluation and testing within a risk management process"* as recognized by FDA. The following endpoints were evaluated:

Table 2 Biocompatibility Testing

Test Standard	Acceptance criteria	Result
ISO 10993-5:2009, Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	Non- Cytotoxic	Pass
ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization	Non-Sensitizing	Pass
	Non-irritating	Pass

Electrical Safety and Electromagnetic Compatibility testing

Electrical Safety and Electromagnetic Compatibility testing was performed on a sample of battery and battery chargers in the subject device and found to conform with the following test standards.

Table 3 EMC and Electrical Safety Testing

Test Standard	Test description
IEC 60601-1-2 Edition 4.0 2014-02	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
IEC/EN 61000-3-2:2014	Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
IEC/EN 61000-3-3:2013	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection
IEC/EN61000-4-2 Edition 2.0 2008-12,	Electromagnetic compatibility (EMC)- Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test

IEC/EN61000-4-3 Edition 3.2 2010-04,	Electromagnetic compatibility (EMC)- Part 4-3: Testing and measurement techniques – Radiated, radiofrequency, electromagnetic field immunity test
IEC/EN61000-4-4 Edition 3.0 2012-04,	Electromagnetic compatibility (EMC) Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test (EFT)
IEC/EN61000-4-5 Edition 3.1 2017-08,	Electromagnetic compatibility (EMC) Part 4-5: Testing and measurement techniques - Surge immunity test
IEC/EN61000-4-6 Edition 4.0 2013-10,	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
IEC/EN61000-4-8 Edition 2.0 2009-09,	Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test
IEC/EN61000-4-11 Edition 2.1 2017-05,	Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests
EN 61326-2-2:2013	Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. Test configurations, operational conditions and performance criteria for portable test, measuring and monitoring equipment used in low-voltage distribution systems
EN 61326-1:2013	EMC Emissions/Immunity Requirement Changes for Laboratory Equipment
ETSI EN 301 489-1 V2.2.3 (2019-11)	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonized Standard for Electromagnetic Compatibility
ETSI EN 300 328 V2.2.2 (2019-07)	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques
FCC 47 CFR 15 Subpart B	Unintentional Radiators
IEC 62368-1:2018	Hazard-based electrical safety standard for IT equipment and Audio-Visual products

IEC 62133-2 Edition1.0 2017-02	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and batteries made from them, for use in portable applications - Part 2: Lithium systems
IEC 60335-2-29:2016	Safety of household and similar electrical appliances Part 2-29: Requirements for battery chargers

Software Verification and Validation Testing

Software Verification and Validation Testing was conducted per the requirements of ANSI AAMI IEC 62304:2006/A1:2015. ***Level of Concern:*** The Level of Concern for the subject device software is moderate. This determination is based on answering the questions in *the FDA Guidance Document "FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.*

FCC Radio Frequency Testing

The Radiofrequency wireless technology was tested to FCC requirements and found to comply with *47 CFR 15.249*.

Wireless Co-existence Testing:

The performance of WHILL Model C2 was evaluated in an environment with other WHILL Model C2 devices and with different types of 2.4 GHz wireless devices. The device met all specified requirements listed in *ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence*.

Usability Testing

Usability was validated following IEC 62366-1:2015.

Mechanical and acoustic Testing

Not Applicable.

Animal Study

Animal performance testing was not required to demonstrate the safety and effectiveness of the device.

Human Clinical Performance Testing

Clinical testing was not required to demonstrate the safety and effectiveness of the device

XI. Comparison with Primary Predicate Device and Reference Device 1

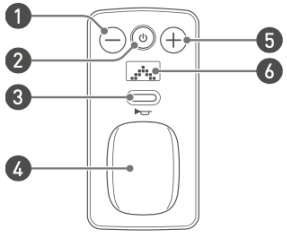
Table 4 Comparison of Model C2 with primary predicate (K153543) and Reference Device 1 (K182576)

Device	Subject Device WHILL Model C2	Primary Predicate Device WHILL Model M (K153543)	Reference Device 1 Solax Powered Wheelchair, model: S7102 (K182576)	Remark
Manufacturer	Whill, Inc.	Whill, Inc.	Dongguan Prestige Sporting Goods Co., Ltd	Same
510K Number	Unknown	K153543	K182576	-
Common or Usual Name	Powered Wheelchair	Powered Wheelchair	Powered Wheelchair	Same
Product Code	ITI	ITI	ITI	Same
Product Classification	Class II	Class II	Class II	Same
Classification Name	Powered Wheelchair	Powered Wheelchair	Powered Wheelchair	Same
Regulation Number	21 CFR 890.3860	21 CFR 890.3860	21 CFR 890.3860	Same
INDICATIONS FOR USE				
Indications for Use	The intended use of the Model C2 powered wheelchair is to provide outdoor and indoor mobility to persons limited to a seated 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.	The intended use of Solax Powered Wheelchair is to provide mobility to adults, limited to a seated position that have capability to operate a few simple controls and the ability to control a powered wheelchair.	-Same as the primary predicate -Similar to Reference Device 1. The primary indication of the subject and the Reference Device 1 is to assist users with mobility
Type of Use	Over the Counter (OTC Only)	Prescription (RX Only)	Over the Counter (OTC Only)	Rationale in Note 11
PHYSICAL CHARACTERISTICS COMPARISON				
			Not available	

Device Construction	Solid aluminum frame	Welded nut and steel	Aluminum frame	SE-Note 1 to the primary predicate device -Same as the Reference Device 1
Device Length	38.8"	37"- 42" (depending on foot plate setting)	27.1654″ (610 mm)	SE-Note 1
Device Width	21.8"	23.6"	23.6″ (600 mm)	SE-Note 1
Device Height	29.3 – 37.2″	Approximately 27.5″ (Varilite Icon Back System Low on lowest seat height) to 36.8″ (Varilite Icon Back System Tall on highest seat height)	35.8″ (910mm)	SE-Note 1
Number of wheels	4	4	4	same
Front Wheel Diameter	10.11"	9.8″	6"	SE-Note 2
Rear Wheel Diameter	10.43"	12.5"	9"	SE-Note 2
Ground Clearance	3"	3.5"	Not available	Similar. The minor difference does not affect the safety and effectiveness of the device
Battery pack	1 rechargeable lithium-ion battery Ratings: 25.3 V 10.5Ah	1 set of two 12V rechargeable lead acid batteries connected in series Ratings: 12V DC 50 Ah (per battery)	rechargeable lithium-ion battery Ratings: 25.9V30AH	SE-Note 3
Number of lead acid batteries (gel or dry acid)	None	2	Not available	Not applicable. Subject device does not have gel or dry acid batteries. Hence the risk associated with the gel or dry acid in the subject device is eliminated Also see SE-Note 3
Battery type and number of batteries (pack)	Lithium-ion number of batteries: 1	Dry lead acid (non-spillable) number of batteries: 2	Lithium-ion	SE-Note 3

Charger	Type: off-board Rated DC output voltage: 24.9V DC Rated current output: 2.4A DC	Type: off-board Rated voltage output: 24V DC Rated current output: 6A DC	Type: off-board Rated DC output voltage: 24V DC Rated current output: 2A DC	SE-Note 3
Battery Type	Lithium-ion	Lead-acid	Lithium-ion	SE- Note 3 for primary predicate Same as the Reference Device 1
Battery weight	6.0 lbs.	32.2 lbs. (per battery)	17.6 lbs. (8 kg)	
OPERATING CHARACTERISTICS				
Operating environments	Indoor/outdoor uses	Indoor/outdoor uses	Not available	Same
Maximum Weight Capacity	300lb (136kg)	220lb (100 kg)	220lb (100 kg)	SE-Note 5 to primary predicate -Same as Reference Device 1
Maximum forward speed (maximum safe speed)	5 mph	5.5 mph	3.8 mph (6.2 Km/hr.)	SE-Note 4
Braking System	Electromagnetic	Electromagnetic	Electromagnetic	Same
Braking mechanism in case of electrical Brake Failure	Normally closed brakes (The "normally closed" brakes are by default engaged on the motors, preventing rotation, when the device is powered off or when electrical power is lost. Detailed description of braking system is provided in ***Vol 10- Device description, Pg 24.***	Normally closed brakes (The "normally closed" brakes are by default engaged on the motors, preventing rotation, when the device is powered off or when electrical power is lost. Detailed description of braking system is provided in	Not available	Both the subject and predicate devices uses the same operating principle during an electric brake failure.
Minimum braking distance from max speed	1500 mm (1.5 m)	1400 mm (1.4 m)	Not available	The braking distance depends on the motor controller design and the maximum weight capacity. The difference between subject device and predicate device is negligible (only 10cm) and mainly due to the subject's device's higher weight capacity (136kg vs 100kg). Both devices comply with ISO 7176-3 Requirements. The difference does not

				raise any safety or effectiveness issues.
Turning Radius	30"	28"	Not available	SE-Note 1
Obstacle Climbing Height (Highest curb clearance)	2”	3”	1.96” (50 mm)	SE-Note 1
Drive system	2 Wheel Drive (Rear wheel drive)	All Wheel Drive	2 Wheel Drive (Rear wheel drive)	SE-Note 6 -Same as Reference Device 1
Dynamic Stability (maximum safe operational incline in degrees with highest center of gravity)	Measured posteriorly: 10º Measured anteriorly: 10º Measured sideways: 10º	Measured posteriorly: 10º Measured anteriorly: 10º Measured sideways: 10º	Not available	Same
Driving Range (full battery charge)/ Maximum distance on fully battery charge	11 miles	12 miles	17.18 miles (27.65 km)	SE-Note 5
On/Off Button	Yes, Power Button on the control pad.	No, Mode Switch (pull away or towards the user) located on the opposite device arm	Not available	Better operability in the subject device.
Speed Settings	4	3	Not available	SE-Note 4
Speed Limit	All the speed settings are in fall within the high control speed limit of 5 mph Detailed information is the ***Vol 10-Device Description, pg.16, Table 6***	Low: Not measured Medium: Not measured High: 5.5 mph	Not available	-
Battery Charging Time	~5 hours	~8 hours to 80%	6~8 hours	The subject device’s battery charges faster
DESIGN FEATURES				
Motor	Brushless DC motor (2 pcs) Rated output: 150W each	Brushed DC motor (2 pcs) Rated output: 800W each	Rated output: 24V 200W	SE-Note 7
Motor controller	Manufacturer: WHILL Model: 21-00011-0	Manufacturer: PG Drives Technology Model: R-Net PM120	PG VR2 60A	SE-Note 7
Joystick Location	Left or right arm	Left or right arm	Left or right arm	Same
Joystick	Users can select the WHILL mouse controller, WHILL easy-grip controller, or a Body point controller.	Users can select the WHILL mouse controller, WHILL easy-grip controller, or a Body point controller.	Not available	Same

User control interface	User controls are housed in a single component—the control pad subassembly. The control pad subassembly may be placed on either the right- or left-hand side of the device to match the user's preference. The control pad subassembly contains the input elements shown below.  ❶ Speed select button "–" Decreases the maximum speed. ❷ Power button Turns on/off the device. ❸ Sound button Turns on/off the sound. ❹ Joystick Controls the forward, backward, left, and right movements. The degree of joystick inclination can also control acceleration and deceleration. ❺ Speed select button "+" Increases the maximum speed. ❻ Display	User controls are separated into two components: directional controller subassembly and indicator subassembly—one subassembly for each hand. The indicator subassembly houses a mode switch knob that can switch the device on/off or into a low, medium, or high-speed profile, indicated by visual markings on the subassembly.  The indicator subassembly also houses LED indicators that denote power on/off, battery charge level, and error code.	The controller with a joystick attaches to either armrest and allows the rider to control the movement and velocity of the powered wheelchair	Easy access to device controls and better operability in the subject device
Arm supports	Lift type: rotates up and out of the way when the arms are rotated to a vertical position.	Lift type: rotates up and out of the way when the arms are rotated to a vertical position.	Not available	Same
Seat Cushions	WHILL original	Varilite Meridian	Not available	SE-Note 8
Back Supports	WHILL original	Varilite Icon	Not available	SE-Note 8
Powered Positioning Configurations	No	Seat slide	Not available	Subject Device-Model C2 doesn't have any powered positioning

				configurations. The difference does not adversely affect the safety and effectiveness of the device.
Wheelchair Tie Downs	None	Yes (optional)	None	Note 12
Seat Widths	16", 18" and 20"	16"	Not available	Similar
Seat Depths	16", 18" and 20"	16",18" and 20"	Not available	Similar
Back support Height	13.4 – 18.1″	20"	Not available	Similar. Difference does not adversely affect the safety and effectiveness of the device
Front Wheel Type	Omni-wheel	Omni-wheel	solid wheel	Same
Rear Wheel Type	Standard: Airless tire	Standard: Airless tire	solid wheel	Same
Anti-tip Wheels	Rear anti-tip wheels	Rear anti-tip wheels	two rear anti-tip wheels	Same
Pressure relief handles	No	Yes	Not available	Note 13
Seat Slide	No	Yes	Not available	Note 14
Tail lamps (2)	Red LED lights	Red LED lights (always on)	Red lights	Same
Disassembly	Users can disassemble model C2 without using tools into four components: Seat, Front Drive Base, Rear Drive Base, and Battery.	Model M cannot be disassembled	cannot be disassembled	The subject device can be disassembled for easy transportation. Note 15
Non-Clinical Performance Testing				
Performance Testing	wheelchair conforms to the ISO 7176 standards	Detailed performance testing conducted to RESNA WC-1, WC-2, and WC-4 standards	wheelchair conforms to the ISO 7176 standards	Similar
Flammability Testing	WHILL-manufactured specialty cushion that tested to ISO 8191-1/8191-2 that is equivalent to ISO 7176-16	Medical purpose cushion tested to RESNA WC3 and ISO 8191-1/8191-2. Plastics -UL-94	ISO 7176-16, Second edition 2012-12-01, Wheelchairs - Part 16: Resistance to ignition of postural support devices	Similar
Biocompatibility	Surface-contacting parts tested to ISO 10993	Surface-contacting parts tested to ISO 10993	Not available	Same
Usability Testing	IEC 62366:2007: Medical Devices – Application of Usability Engineering to Medical Devices	IEC 62366:2007: Medical Devices – Application of Usability Engineering to Medical Devices Performed on 20 Subjects	IEC 62366 Medical devices – Application of usability engineering to medical devices Edition 1.0, 2007	Same
Environmental Conditions				
Operating Conditions	5 to 104 degrees F (-15 to 40 degrees C)	-13 to 122 degrees F (-25 to 50 degrees C)	Not available	Note 9

Storage Conditions	5 to 104 degrees F (-15 to 40 degrees C)	-40 to 149 degrees F (-40 to 65 degrees C)	Not available	Note 9
Miscellaneous Safety Test Results				
Battery recharger	Meets the requirements (PASSED) in ISO 7176-14:2008, ISO 7176-21:2009, IEC 60335-2-29, EN 60601-1-2, EN 61326-2 and CISPR 11:2015 A1:2016 A2:2019 Group 1 Class B.	Meets the requirements (PASSED) in ANSI/RESNA WC-2:2009 Section 21: Requirements and Test Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Motorized Scooters	Not available	-
Flame retardant test of the upholstery material	• Upholstered composite parts (seat cushion and back cushion): passed ISO 8191-2 • Lap belt: passed EN 1021-1, EN 1021-2, ISO 8191-2 • Power and control systems -PASS	• Upholstered composite parts (cushion cover and foam): passed ISO 8191-1 and ISO 8191-2 • Lap belt: passed ISO 7176-16 • Plastic parts: passed UL94	Not available	-
Ground leakage current	Not applicable (no on-board charger)	Not applicable (no on-board charger)	Not available	-

Comparison with Reference Device 2

The subject device includes an additional Radio Frequency wireless technology feature, where the device can be controlled with a smartphone app, supported on iOS, Android, via Bluetooth Low Energy (BLE). To account for the additional feature, e-motion-M25(K192618) is chosen as the reference device 2. *Table 2* demonstrates that the Radio Frequency wireless technology in the subject device and its reference device are substantially equivalent.

Table 5 Comparison of Model C2 with reference device 2 (K192618)

Radio Frequency Wireless Technology			
Features	**Reference Device 2** **e-motion M25(K192618)**	**Subject Device** **WHILL Model C2**	**Remark**
Product Code	ITI	ITI	Same
Product Classification	Class II	Class II	Same
Indications for Use	The e-motion M25 is a Power Assist Wheelchair Conversion Kit and suitable for manual wheelchair users who are limited in their field of activities because of their physical	The intended use of the Model C2 powered wheelchair is to provide outdoor and indoor mobility to persons limited to a seated position that is capable of operating a powered wheelchair.	SE Note 10

	conditions. The device can expand its field of activities by assisting its wheelchair operating force		
Classification Name	Powered Wheelchair	Powered Wheelchair	Same
Regulation Number	21 CFR 890.3860	21 CFR 890.3860	Same
Type of wireless technology	IEEE 802.15.4 (Bluetooth Low Energy)	IEEE 802.15.4 (Bluetooth Low Energy)	Same
FCC compliance	CFR47, Part 15	CFR47, Part 15	Same
Wireless Coexistence Compliance	ANSI C63.27-2017 American National Standard for Evaluation Of Wireless Coexistence	ANSI C63.27-2017 American National Standard for Evaluation Of Wireless Coexistence	Same
EMC Compliance	ISO 7176-21:2009	ISO 7176-21:2009	Same
Wireless functions	Emergency stop, Operating mode (on/standby)	adjust speed, acceleration, turning settings, and lock the device when it is unattended	Similar. Subject device has additional features that does not affect its safety and effectiveness
Smartphone App	iOS and Android	iOS and Android	Same
Wireless RF frequency range	2.402 GHz to 2.480 GH	2.402 GHz to 2.480 GH	Same
Wireless RF maximum output power	5dBm	6dBm	Minor difference. It does not affect the subject devices functionality
Wireless operating range	10m	10m	Same

- Note 1: "Device weight," "turning radius," "Obstacle Climbing Height" comply with *ISO 7176-5 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space*
- Note 2: The difference in "wheel diameters" does not affect the device's safety and effectiveness. The subject, primary, and reference device 1 have passed the same criteria ("class A" criteria) determined by *EN 12184:2014 Electrically powered wheelchairs, scooters, and chargers.*
- Note 3 Battery, Battery charger:
    - Battery lithium-ion batteries are used in the subject device over the lead-acid batteries in the predicate device. The batteries have passed the testing to *IEC 62133-2:2017 (Secondary Cells and Batteries containing Alkaline or other Non-Acid Electrolytes – Safety Requirements for Portable Sealed Secondary Cells, and Batteries made from them, for use in Portable Applications),(**Table 3**)* AND the subject device was tested to the *ISO 7176 standard* (***Table 1)***
    - Battery Charger: Although the chargers are the same type of off-board chargers and possess the same input and slightly different output voltages, *IEC 60335-2-29:2016 Household and Similar Electrical Appliances - Safety - Part 2-29: Particular Requirements for Battery Chargers*

- Note 4 "Maximum speed forward" and "speed settings" comply with *ISO 7176-6 Wheelchairs – Part 6: Determination of maximum speed, acceleration, and deceleration of electric wheelchairs*
- Note 5 "Energy consumption," "Driving Range," and "Maximum capacity" comply with *ISO 7176-4 Wheelchairs – Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range*
- Note 6 "Drive System" complies *ISO 7176-14 Wheelchairs – Part 14: Power and control systems for electrically powered wheelchairs and scooters. Requirements and test methods.*
- Note 7 Motor and Motor controller
    - Motors: The subject device uses Brushless DC motors over brushed DC motors to achieve lightweight and portability. Please see *Table 6* for the comparison

Table 6 Comparison of Brushless DC Motors over Brushed DC Motors

Features	Model M: R-net module	Model C2: WHILL motor controller
Compatible motor type	Brushed DC motors - heavy - bulky - low cost - simple control mechanism	Brushless DC motors - lightweight - compact - high cost - sophisticated control mechanism
Optimization	Difficult to adjust for WHILL devices due to minimal motor control parameters	Fully optimizable to match WHILL device characteristics

- Motor controller: WHILL Motor controller is used over R-Net power module. The motor and the motor controller. The motor and the motor controller comply with *ISO 7176-14 Wheelchairs – Part 14: Power and control systems for electrically powered wheelchairs and scooters. Requirements and test methods*

Note 8: The difference in the device materials does not affect the safety and effectiveness of the device. The subject device has been tested to Flammability *per ISO 8191-2:1988 Furniture — Assessment of ignitability of upholstered furniture — Part 2: Ignition source: match-flame equivalent, a normative reference in EN 12184:2014 Electrically powered wheelchairs, scooters, and chargers.*

- Note 9: The difference in environmental conditions comes from the different battery types used in the subject device and the primary predicate. These differences do not affect the subject device's safety and effectiveness

- Note 11: The rationale for the subject device meeting the OTC designation in comparison with the Primary Predicate Device is as follows:

1. The indication of Model C2 does not require a physician's diagnosis.
    - Neither Model C2 nor Model M was indicated for any specific disease that requires a physician's diagnosis.
2. The use of Model C2 does not involve a physician or Healthcare professional's (HCP) intervention.
    - Neither Model C2 nor Model M requires an HCP to train the user.
    - Neither Model C2 or Model M's IFU contains warnings that require an HCP's intervention or consultation.
    - The Model C2 IFU is designed to be self-sufficient in training and guiding users in safe and effective use of the subject device and is shown to be adequate as the sole instructional material of the non-prescriptive Model C2 device in Japan.
3. The maximum weight capacity of Model C2 has been increased to 300lbs from Model M's 220lbs to accommodate a wider patient population on par with most wheelchairs on the market without the need for physician's screening.

The rationale for the subject device meeting the OTC designation in comparison with Reference Device 1 (K182576) is as follows:

1. Neither the subject device nor Reference Device 1 requires a physician's diagnosis. Both devices are indicated for the same patient population without specific disease conditions.
2. Neither device involves a physician or HCP's intervention.
3. Both devices share highly similar technological features and performance specifications as shown in Table 1. The justification for the only notable feature difference of device disassembly is documented in Note 15 below and this feature has been verified and validated to ensure that all new risks are mitigated.

- Note 12: The tie downs were removed from Model C2, because the wheelchair is not intended to be used as a seat in a motor vehicle. The removal of the tie downs eliminates the risk of foreseeable misuse. The Model C2 IFU contains a warning against the use of the device as a seat in a motor vehicle.

- Note 13: Although Model C2 does not have dedicated pressure relief handles as the predicate device, both arm supports on Model C2 are capable of being used for the same purpose. The arm support has been tested in Verification Test ID# TCL02-W-036 to withstand 1076N of downward force repeatedly for 20,000 cycles. 1076N is the equivalent of the max load capacity of Model C2. The test demonstrates that Model C2 users may use the either one or both arm supports for pressure relief

- Note 14: The seat slide feature was removed from Model C2 to eliminate the risk of foreseeable misuse from an unstable extended seat, the pinch point hazard or the collision hazard of a retracting seat.

- Note 15: The primary predicate device (Model M) cannot be disassembled, making it difficult for transportation. The subject device on the other hand can be disassembled into 4 transportable parts. The disassembly of the wheelchair in the subject device allows for smaller storage and easy transportation space, which is easier, safer and convenient for Model C2 users. These differences in wheelchair disassembly in predicate device and subject device does not impact the safety and effectiveness of the device.

The difference from the reference device 2

- Note 10 indication for use is different, but the primary indication is to assist users with mobility. The subject device has a wireless functionality to control the device with the same technological means as the reference device 2. Hence both the subject and the reference 2 devices are considered substantially equivalent concerning the aspects of RF Wireless technology.

XII. CONCLUSIONS

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 WHILL Model C2 (Subject Device) described herein has an equivalent intended use and the same fundamental technology as the cleared primary predicate device, the WHILL Model M (K153543), and the reference device 1, Solax Powered Wheelchair (K182576). The additional wireless technology feature in the subject device is comparable to the reference device 2, the e-motion-M25 (K192618). Based on the performance data presented for the design differences between the subject device and primary predicate device, it can be concluded that the WHILL Model C2 is as safe and effective as, and substantially equivalent to, the predicate device and reference devices.