June 7, 2022

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

Re: K221438
Trade/Device Name: WHILL Model F
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: May 16, 2022
Received: May 17, 2022

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,

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

Enclosure

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)*
K221438

Device Name
WHILL Model F

Indications for Use *(Describe)*
The intended use of the WHILL Model F 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

K221438

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: April 15, 2022

II. DEVICE

Name of Device:	WHILL Model F
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 C2
- 510(k): K213383
- Classification Name: Physical Medicine
- Regulation: 21 CFR § 890.3860
- Regulatory Class: Class II
- Product Classification Code: ITI

IV. REFERENCE DEVICE 1

Reference Device 1

- Manufacturer: Nanjing Jin Bai He Medical Apparatus Co. Ltd.
- Trade Name: Powered Wheelchair DYW30A(D09)
- 510(k): K170787
- 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 C2 (K213383) (hereafter the "predicate device").

The WHILL Model F is an indoor/outdoor, foldable battery-operated 2-wheel drive (rear-wheel drive) powered wheelchair. It has two arm rests, a seat belt, a foldable backrest, a seat cushion, a foldable frame, two motors, two electromagnetic brakes, an electric motor controller, and a lithium-ion battery with a dedicated off-board battery charger. The wheelchair is powered by a 25.3 V 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 one of the arm rests. When the joystick is released, the electromagnetic brakes will be actuated, and the power wheelchair is slowed to a stop.

As with all conventional 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 arm rests to fit the user's body. The space between the two arms and the height of the arm rests can be adjusted based on the user's seating requirements.

Model F contains a new folding feature, not available on the predicate device. The foldable technology is like the legally marketed DYW30A(D09) powered wheelchair (K170787) (hereafter the "reference device").

The subject 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 can also display 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.

The device supports a maximum weight of 253.5lb (115 kg), including the weight of the occupant and any carried items. It has a maximum driving range of 12.4 miles (20 km) with a maximum speed limit of up to 3.7mph (6 km/h).

VI. INDICATIONS FOR USE

The intended use of the WHILL Model F 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 C2 (K213383). The following characteristics were compared between the subject device and the predicate devices to demonstrate substantial equivalence:

- ***Indications for Use***: WHILL Model F has the same indications of use, principles of operation, and mostly identical technical characteristics as the previously cleared primary predicate device, WHILL Model C2 (K213383). 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 shares identical materials used in surface contacting components as the primary predicate device. All 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 can be folded for storage and transportation, uses casters as the front-wheels drive and does not have suspension system on its rear drive wheels. These key features have been evaluated for safety and performance and 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 share identical batteries. 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-IX.*

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE REFERENCE DEVICE 1

The subject device can be folded for storage and transportation. Hence Powered Wheelchair-DYW30A(D09) (K170787) manufactured by Nanjing Jin Bai He Medical Apparatus is chosen as the reference device 1 to account for this design feature.

- ***Indications for Use***: WHILL Model F has similar indications of use, principles of operation, and similar technical characteristics as the reference device 1, Powered Wheelchair DYW30A(D09) (K170787). 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 detail on the surface contacting components and biocompatibility test of the reference device 1 in its 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 *IEC62133-2* standard.
- ***Performance Testing***: Both the reference device 1 and subject devices were subjected to the same performance tests listed below in Section-I*X.*

IX. 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 and 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 were tested to the ISO 7176 standard. These standards are listed in 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 F with predicate device and reference device 1.

Subject Device WHILL Model F	Primary Predicate Device WHILL Model C2 (K213383)	Reference Device 1 Powered Wheelchair
ISO 7176-1 Third edition 2014-10-01 Wheelchairs -Part 1: Determination of static stability	Identical to subject device	Identical to subject device
ISO 7176-2 Third edition 2017-10 Wheelchairs - Part 2:Determination of dynamicstability of electrically powered wheelchairs	Identical to subject device	ISO 7176-2:2001 Wheelchairs - Part 2:Determination of dynamicstability of electric wheelchairs
ISO 7176-3 Third edition 2012-12-15 Wheelchairs -Part 3: Determination of effectiveness of brakes	Identical to subject device	Identical to subject device
ISO 7176-4 Third edition 2008-10-01Wheelchairs - Part 4: Energy consumptionof electric wheelchairs and scooters for determination of theoretical distance range	Identical to subject device	Identical to subject device
ISO 7176-5 Second edition2008-06-01Wheelchairs - Part 5: Determination of overall dimensions, mass and maneuvering space	Identical to subject device	Identical to subject device
ISO 7176-6 Third edition 2018-06 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs	Identical to subject device	ISO 7176-6:2001 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	Identical to subject device	Identical to subject device
ISO 7176-9 Third edition 2009-11-15Wheelchairs - Part 9: Climatic tests for electric wheelchairs	Identical to subject device	Identical to subject device
ISO 7176-10 Second edition 2008-11 01Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs	Identical to subject device	Identical to subject device
ISO 7176-11 Second edition 2012-12-01Wheelchairs - Part 11: Test dummies	Identical to subject device	Identical to subject device

Subject Device WHILL Model F	Primary Predicate Device WHILL Model C2 (K213383)	Reference Device Powered Wheelchair DYW30A(D09) (K170787)
ISO 7176-13: 1989 Wheelchairs - Part 13: Determination of Coefficientof Friction of Test Surfaces	Identical to subject device	Identical to subject device
ISO 7176-14 Second edition2008-02-15 Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods	Identical to subject device	Identical to subject device
ISO 7176-15 First edition 1996-11-15 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling	Identical to subject device	Identical to subject device
ISO 7176-16 Wheelchairs –Part 16: Resistance to ignition of postural supportdevices- ISO 8191-2:1988Furniture — Assessmentof ignitability of upholstered furniture —Part 2: Ignition source: match-flame equivalent	Identical to subject device	Identical to subject device
ISO 7176-21 Second edition2009-04-01Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers	Identical to subject device	Identical to subject device
ISO 7176-22 Second edition2014-09-01 Wheelchairs - Part 22: Set-up procedure	Identical to subject device	N/A
UN 38.3 Recommendationsof the TRANSPORT OF DANGEROUS GOODS, Manual of Test and Criteria,Part III, Lithium metal and lithium-ion batteries	Identical to subject device	N/A

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.

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 andSkin 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 F was evaluated in an environment with other WHILL Model F 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 TestingNot Applicable.

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

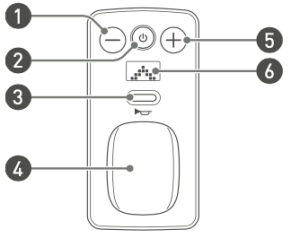
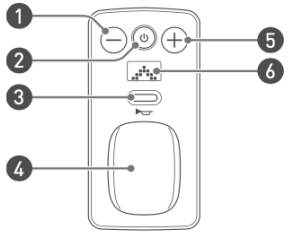
Human Clinical Performance Testing
Clinical testing was not required to demonstrate the safety and effectiveness of the device

X. 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 F (Subject Device) described herein has an equivalent intended use and the same fundamental technology as the cleared primary predicate device, the WHILL Model C2 (K213383), and the reference device, Powered Wheelchair DYW30A(D09) (K170787). 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 F is as safe and effective as, and substantially equivalent to both the predicate device and the reference device.

Device	Subject Device WHILL Model F	Primary Predicate Device WHILL Model C2 (K213383)	Reference Device 1 Powered Wheelchair DYW30A(D09) (K170787)	Remark
Manufacturer	Whill, Inc.	Whill, Inc.	Dongguan Prestige Sporting Goods Co., Ltd	Same
510K Number	Unknown	K213383	K170787	-
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 F 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 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 device is a motor-driven, and indoor transportation vehicle with the intended use to provide mobility to a disabled or an elderly person limited to a seated position.	-Same as the primary predicate -Similar to Reference Device. The primary indication of the subject and the Reference Device is to assist users with mobility
Type of Use	Over the Counter (OTC Only)	Over the Counter (OTC Only)	Over the Counter (OTC Only)	Same
PHYSICAL CHARACTERISTICS COMPARISON				
			Not available	
Device Construction	Solid aluminium frame	Solid aluminium frame	6063 Aluminium Alloy	Same as primary predicate

Device weight	58.9 lbs.	114 lbs.	Not available	SE-Note 1
Device Length	36.8"	38.8"	37.4"	SE-Note 1
Device Width	21.8"-23.8"	21.8"	22.6"	SE-Note 1
Device Height	31.6"	29.3 – 37.2"	36.2"	SE-Note 1
Number of wheels	4	4	4	same
Front Wheel Diameter	7.6" (194 mm)	10.11"	Not available	SE-Note 2
Rear Wheel Diameter	8.25"	10.43"	Not available	SE-Note 2
Ground Clearance	2.4"	3"	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 rechargeable lithium-ion battery Ratings: 25.3 V 10.5Ah	2 rechargeable lithium-ion battery Ratings: 24V 6AH	Same as the predicate device.
Charger	Type: off-board Rated DC output voltage: 28.49V DC Rated current output: 2.4A DC	Type: off-board Rated DC output voltage: 28.49V DC Rated current output: 2.4A DC	Type: off-board Rated DC output voltage: 24V DC Rated current output: 2A DC	Same as the predicate device
Battery Type	Lithium-ion	Lithium-ion	Lithium-ion	Same
Battery weight	6.0 lbs.	6.0 lbs.	17.6 lbs. (8 kg)	Same as the primary predicate and lighter than the Reference Device 1
OPERATING CHARACTERISTICS				
Operating environments	Indoor/outdoor uses	Indoor/outdoor uses	Indoor use	Same as the primary predicate. The device is Designed for indoor and outdoor use. Based on the testing as mentioned in SE-Note 1 , SE-Note 2 , the device poses no safety and effectiveness concerns.
Maximum Weight Capacity	253lb (115 kg)	300lb (136kg)	220lb (100 kg)	SE-Note 5
Maximum speed	3.7 mph	5 mph	3.75 mph (6 km/h)	SE-Note 5

forward				
Braking System	Electromagnetic	Electromagnetic	Electromagnetic	Same
Turning Radius	30.7"	30"	32.5”	SE-Note 1
Obstacle Climbing Height	1.4”	2”	1.36” (34.5 mm)	SE-Note 1
Drive system	2 Wheel Drive (Rear wheel drive)	2 Wheel Drive (Rear wheel drive)	2 Wheel Drive (Rear wheel drive)	Same
Dynamic Stability (incline)/Maximum allowable inclination	10º	10º	Not available	Same
Driving Range (full battery charge)	12.4 miles	11 miles	17.18 miles (27.65 km)	SE-Note 5
On/Off Button	Yes, Power Button on the control pad.	Yes, Power Button on the control pad.	Not available	Same
Speed Settings	4	4	Not available	Same
Battery Charging Time	~5 hours	~5 hours	6~8 hours	Same as the primary predicate device. The Subject device charges faster than the Reference Device 1.
DESIGN FEATURES				
Motor	Manufacturer: NIDEC Motor type: brushless DC motor Rated output: 150W x 2 PCS	Manufacturer: NIDEC Motor type: brushless DC motor Rated output: 150W x 2 PCS	Not Applicable	Motor type and Rated output is same. Physical size is smaller and lighter than the predicated device. Subjective device were conducted same ISO7176 series test and those results show the differences do not raise any safety issues.
Motor controller	Manufacturer: WHILL Model: 21-00011-0	Manufacturer: WHILL Model: 21-00011-0	Not Available	Same enclosure and similar software
Joystick Location	Left or right arm	Left or right arm	Left or right arm	Same
User control interface	User controls are housed in a single component—the control pad subassembly. The control pad	User controls are housed in a single component—the control pad subassembly. The control pad	Not Available	Same enclosure and similar software.

	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.  1 Speed select button "–" Decreases the maximum speed. 2 Power button Turns on/off the device. 3 Sound button Turns on/off the sound. 4 Joystick Controls the forward, backward, left, and right movements. The degree of joystick inclination can also control acceleration and deceleration. 5 Speed select button "+" Increases the maximum speed. 6 Display	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.  1 Speed select button "–" Decreases the maximum speed. 2 Power button Turns on/off the device. 3 Sound button Turns on/off the sound. 4 Joystick Controls the forward, backward, left, and right movements. The degree of joystick inclination can also control acceleration and deceleration. 5 Speed select button "+" Increases the maximum speed. 6 Display		
Arm rest	Height of arm rest can be adjusted in 3 Stages: 26.4 inches, 27.2 inches **OR** 28.0 inches Space between arm rests can be adjusted: Wide (18.8 inches) **OR** Standard (16.9 inches)	Using with tool, Height of armrest are adjustable in 4 Stages. Lift type: rotates up and out of the way when the arms are rotated to a vertical position.	Not available	Rotation is implemented for a lightweight design. According to the subject device, the armrests can be adjusted without using additional tools as with the predicate device. The arm rest can be easily and quickly adjusted during actual

				use in the subject device. The ISO7176 test report shows the differences do not raise any safety and performance issues
Seat Cushions	WHILL original	WHILL original	Not available	Similar. Cushion cover is mesh type and it does not affect safety, especially anti-flame ability and effectiveness of device.
Back Supports	WHILL original	WHILL original	Not available	Similar. Cover is mesh type and it does not affect safety, especially anti-flame ability and effectiveness of device.
Powered Positioning Configurations	No	No	Not available	Same
Wheelchair Tie Downs	None	None	Not available	Same
Seat Widths	17.7"	16", 18" and 20"	Not available	Similar. Seat width is only available in one size. Minor differences do not adversely affect the safety and effectiveness of the device
Seat Depths	15.7"	16", 18" and 20"	Not available	Similar. Seat depths are only available in one size Minor differences do not adversely affect the safety and effectiveness of the device

Back support Height	15.19"	13.4 – 18.1″	Not available	Similar. Back support height is only available in one size. Minor differences do not adversely affect the safety and effectiveness of the device
Front Wheel Type	Caster wheels with solid wheel	Omni-wheel	solid wheel	SE Note 2
Rear Wheel Type	air-filled tires	Standard: Airless tire	solid wheel	SE Note 2
Anti-tip Wheels	Rear anti-tip wheels	Rear anti-tip wheels	Rear anti-tip wheels	Same
Pressure relief handles	No	No	Not available	Same
Seat Slide	No	No	Not available	Same
Tail lamps (2)	No LED lights Rear reflector are equipped for safety.	Red LED lights	Not available	The absence of the LED light and light weight feature in the subject device will not impose any additional risks and does not raise any safety and effectiveness. A safety feature is considered, the device is equipped with rear reflectors
Foldable	Foldable. Foldable frame	Users can disassemble model C2 without using tools into four components: Seat, Front Drive Base, Rear Drive Base, and Battery.	Foldable. Two foldable arm rests Foldable frame	SE Note 6
Non-Clinical Performance Testing				
Performance Testing	wheelchair conforms to the ISO 7176 standards	wheelchair conforms to the ISO 7176 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	WHILL-manufactured specialty cushion that tested to ISO 8191-1/8191-2 that is equivalent to ISO 7176-16	ISO 7176-16, Second edition 2012-12-01, Wheelchairs - Part 16: Resistance to ignition of postural support devices	Similar
Biocompatibility	Surface-contacting parts complies with ISO 10993	Surface-contacting parts tested to ISO 10993	Not available	The results of the biocompatibility tests conducted on Model C2 are applicable to

				Model F because the surface contacting parts are the same. Therefore, no additional testing was performed on the subject device
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	Not Available	Same
Environmental Conditions				
Operating Conditions	5 to 104 degrees F (-15 to 40 degrees C)	5 to 104 degrees F (-15 to 40 degrees C)	Not available	Same
Storage Conditions	5 to 104 degrees F (-15 to 40 degrees C)	5 to 104 degrees F (-15 to 40 degrees C)	Not available	Same
Radio Frequency Wireless Technology				
Type of wireless technology	IEEE 802.15.4 (Bluetooth Low Energy)	IEEE 802.15.4 (Bluetooth Low Energy)	Not Applicable	Same
FCC compliance	CFR47, Part 15	CFR47, Part 15	Not Applicable	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	Not Applicable	Same
EMC Compliance	ISO 7176-21:2009	ISO 7176-21:2009	ISO 7176-21:2009	Same
Wireless functions	adjust speed, acceleration, turning settings, and lock the device when it is unattended	adjust speed, acceleration, turning settings, and lock the device when it is unattended	Not Applicable	Same
Smartphone App	iOS and Android	iOS and Android	Not Applicable	Same
Wireless RF frequency range	2.402 GHz to 2.480 GH	2.402 GHz to 2.480 GH	Not Applicable	Same
Wireless RF maximum output power	6dBm	6dBm	Not Applicable	Same
Wireless operating range	10m	10m	Not Applicable	Same
Smartphone App	IEEE 802.15.4 (Bluetooth Low Energy)	IEEE 802.15.4 (Bluetooth Low Energy)	Not Applicable	Same

The following technological characteristics are different from the primary predicate and Reference device 1.

- Note 1: "Device weight," "Device Length" Device Height "turning radius," "Obstacle Climbing Height" "Ground Clearance" comply with *ISO 7176-5 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space*

    - Device weight, length and height: Compared with the predicate device, light weight is one of the main features of subject device. The ratio of the weight/power for the subject device is 58.9 lbs. / 150 W = 0.39 lbs./W and the predicate device is 114 lbs./150 W= 0.76 lbs./W. The subject device will use one joule energy per second to push 0.39 pounds of wheelchair weight, and the predicate device will use one joule energy per second to push 0.76 pounds of wheelchair weight. That is to say, the subject device consumes less battery power than predicate device. The subject device has passed the testing to Per testing result, lighter weight itself does not affect the safety and effectiveness of the device. Besides light weight, the reliability, safety and performance of subject device are complied with *EN 12184:2014 Electrically powered wheelchairs, scooters, and chargers.*

    - Turning radius and Obstacle Climbing Height: there are minor differences in the turning radius and Obstacle Climbing Height. The device has passed its testing to *ISO 7176-5 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space* and does not raise any safety and effectiveness concerns

- Note 2:
    - The difference in "wheel diameters" and "wheel type" does not affect the device's safety and effectiveness. The subject and the primary device have passed the same criteria ("class A" criteria) determined by *EN 12184:2014 Electrically powered wheelchairs, scooters, and chargers*.
    - Front Wheel The predicate device is equipped with Omni wheels, while the subject device is equipped with caster wheels. Caster with solid wheel tires makes the wheelchair lightweight and increases the propulsion efficiency of the wheelchair and can cover long distances. The subject has passed tests determined by *EN 12184:2014 Electrically powered wheelchairs, scooters, and chargers* and the differences does not raise any safety and performance concerns

    - Rear Wheel: The subject device has air-filled tires as opposed to the predicate device, which has airless tires. Pneumatic air-filled tires are be preferred due to light weight being a design priority and longer driving range. Air-filled tires are lightweight and shock-absorbing, so they are gentler on the ride. The subject has passed tests determined by *EN 12184:2014 Electrically powered wheelchairs, scooters, and chargers* and the differences does not raise any safety and performance concerns

- Note 3: Battery weight
  - Battery weight: The battery weight is identical to the subject device and lighter than the reference device 1. The battery's light weight makes the subject device light in weight and easy to transport. The battery is complied with UN38.3. Also, 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)*. The battery is able to carry on baggage in airplane. There are no new safety and effectiveness concerns raised for the subject device.

- Note 4 The "Maximum speed forward" is slightly different from the primary predicate. They comply with *ISO 7176-6 Wheelchairs – Part 6: Determination of maximum speed, acceleration, and deceleration of electric wheelchairs* and has passed the testing. The differences do not raise any safety and effectiveness concerns.

- 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.* There are no new safety and performance concerns raised for the subject device.

- Note 6 "Folding design" Model F's folding and light weight design facilitate easy and compact handling. However, Model C2 is difficult to transport down and upstairs, and it requires to disassemble and reassemble every time during storage and transport. Since Model F can be folded and unfolded without any tools, the lightweight and foldable design of the Model F makes available to be checked in airplane travel.