



January 6, 2025

Whill, Inc.
% Bhoomika Joyappa
Senior Regulatory Consultant
Medical Device Academy, Inc.
345 Lincoln Hill Road
Cuttingsville, Vermont 05738

Re: K242760
Trade/Device Name: WHILL Model R
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: November 27, 2024
Received: December 2, 2024

Dear Bhoomika Joyappa:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tushar Bansal -S

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

Indications for Use

Submission Number (if known)

K242760

Device Name

WHILL Model R

Indications for Use (Describe)

The Model R is a motor-driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

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.

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510(k) SUMMARY

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.
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Phone: +819025672984
Contact Person: Tsuyoshi Iriyama
Date Prepared: August 21, 2024

II. SUBJECT DEVICE

Trade Name: WHILL Model R
510(k): K242760
Classification Name: Motorized three-wheeled vehicle
Regulation: 21 CFR § 890.3800
Regulatory Class: Class II
Product Classification Code: INI

III. PREDICATE DEVICE

Manufacturer: Zhejiang Innuovo Rehabilitation Devices Co., Ltd
Trade Name: Mobility Scooter, Model: W3331F
510(k): K222495
Classification Name: Motorized three-wheeled vehicle
Regulation: 21 CFR § 890.3800
Regulatory Class: Class II
Classification Product Code: INI

IV. REFERENCE DEVICE

Manufacturer: Whill, Inc.
Trade Name: WHILL Model F
510(k): K221438
Classification Name: Powered wheelchair
Regulation: 21 CFR § 890.3860
Regulatory Class: Class II
Classification Product Code: ITI

V. DEVICE DESCRIPTION

WHILL Model R is an indoor/outdoor electric scooter that is intended as a mobility aid for elderly persons or persons with reduced mobility. Providing Bluetooth-based radio communications functionalities.

Model R is available in two variants, the 3-wheel model and the 4-wheel model. The 3-wheel scooter has a base with metal alloy frame, one front wheels, two rear wheels, two anti-tip wheels, a seat, an adjustable steering column, a tiller console, 2 electric motors, 2 electromagnetic brakes, a rechargeable lithium-ion battery with an off-board charger.

The 4-wheel scooter has a base with metal alloy frame, two front wheels, two rear wheels, two anti-tip wheels, a seat, an adjustable steering column, a tiller console, 2 electric motors, 2 electromagnetic brakes, a rechargeable lithium-ion battery with an off-board charger.

The only difference between 3-wheel model and 4-wheel model is front drive-base component. The 3-wheel model has a single front tire, while the 4-wheel model has two front tires. Besides this difference in mechanical design, other parts of the device are identical across the two models. Customers can choose a model depending on their preferences and use case.

Model R has a removable lithium-ion battery, a swivel 17-inch-wide seat with two armrests and front and rear LED lights. The battery may be charged either when installed within the device or when removed.

Some components are adjustable to provide user with a comfortable riding position. The inner width and the height of the armrests are adjustable in 3 positions. The seat position from the tiller is adjustable in 4 positions. The seat height is adjustable in 2 positions and the tiller angle is also adjustable. A lap belt is equipped for posture support and for safety.

As with all conventional powered scooters, to drive the Model R, the user sits in the seat and grips the tiller handle around the controller unit which is positioned in front of the user. While gripping the tiller handle, the user uses their fingers to pull the right side of the throttle control lever gently to drive the device forward. The degree at which the throttle control lever is pulled is positively proportional to the speed of the device. When the throttle control lever returns to its original position after the user releases it, the device decelerates and comes to a stop. When the user uses their fingers to pull on the left side of the lever, the device drives backwards. To move to the left, the user turns the tiller handle to the left, and, to move to the right, the user turns the tiller handle to the right.

Model R has Bluetooth-based radio communications capabilities. The user can power on Model R with a physical key, a Bluetooth smart key fob or with a dedicated smartphone app. The user can select speed profiles, turn off and on the front LED light and sound the audible warning device by operating the controller unit.

User can disassemble Model R into four components, i.e. drive base, main body, seat base assembly and battery, without the use of tools when loading into a car for transportation.

The device supports a maximum weight of 147 kg (325 lbs.), including the weight of the occupant and any carried items. The 3-wheel model has a theoretical continuous driving range of 18.7 km (11.6 miles) while the 4-wheel model has a theoretical continuous driving range of 17.2 km (10.7 miles).

VI. INDICATIONS FOR USE

The Model R is a motor-driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

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 W3331F (K222495) manufactured by Zhejiang Innuovo Rehabilitation Devices Co., Ltd. The following characteristics were compared between the subject device and the predicate devices to demonstrate substantial equivalence:

- **Indications for Use:** WHILL Model R has the same indications of use, principles of operation, and mostly identical technical characteristics as the previously cleared primary predicate device, Innuovo W3331F (K222495). Both are indicated for indoor and outdoor mobility to elderly persons with reduced mobility.
- **Materials:** All the subject device's surface-contacting parts are tested to ISO 10993 standards, equivalent to the predicate device.
- **Design:** The subject device uses the same operating principle as the primary predicate device. Both devices can be disassembled for transport or storage. The key differences are that certain functions of the subject device can be controlled remotely via Bluetooth Low Energy. The remote control features of the subject device are nearly identical to those of the reference device. Besides the remote driving feature that is available only on the reference device, the subject device shares all other remote control features with the reference device. Exclusion of the remote driving feature reduces the use-related risks and the security risks of the subject device. Furthermore, the subject device and the reference device share identical wireless communication characteristics, and their wireless features passed the same set of safety and performance testing. As such, the remote control and wireless communication features of the subject device do not raise concerns about safety or effectiveness.
- **Energy Source:** The subject device and the primary predicate are both battery-powered. 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 biocompatibility and performance tests listed below in *Section-IX*.

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE REFERENCE DEVICE

Certain functions of the subject device can be controlled wirelessly via Bluetooth Low Energy.

Hence the Powered Wheelchair- WHILL Model F (K221438) was chosen as the reference device to account for this design feature.

- **Indications for Use:** Although the subject device is a powered scooter, not a powered wheelchair like the reference device. The two devices share highly similar indications for use, intended for use by patients limited to a seated position. Both devices conform to the same set of recognized consensus standards on performance, safety and effectiveness. The subject device has a wireless functionality to control the device with the same technological means as the reference device. Hence, both the subject and the reference devices are considered substantially equivalent concerning the aspects of wireless technology.
- **Materials:** The subject device has similar skin-contacting components tested to ISO 10993 standards..
- **Energy Source:** The subject device and the reference device share the same lithium-ion battery. The lithium-ion battery has been safety tested to *IEC62133-2* standard.
- **Performance Testing:** Both the reference device and subject devices were subjected to the same performance tests listed below in Section-IX.

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 were tested to the ISO 7176 standards. 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 performance testing standards

Standard	Subject Device	Predicate Device	Reference Device	Result
ISO 7176-1:2014 Wheelchairs – Part 1: Determination of static stability	Tested	Tested	Tested	S.E.
ISO 7176-2:2017 Wheelchairs – Part 2: Determination of dynamic stability of electrically powered wheelchairs	Tested	Tested	Tested	S.E.
ISO 7176-3:2012 Wheelchairs – Part 3: Determination of effectiveness of brakes	Tested	Tested	Tested	S.E.
ISO 7176-4:2008 Wheelchairs – Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range	Tested	Tested	Tested	S.E.
ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass and manoeuvring space	Tested	Tested	Tested	S.E.
ISO 7176-6:2018 Wheelchairs – Part 6: Determination of maximum speed of electrically powered wheelchairs	Tested	Tested	Tested	S.E.
ISO 7176-7:1998 Wheelchairs – Part 7: Measurement of seating and wheel dimensions	Tested	Tested	Tested	S.E.
ISO 7176-8:2014 Wheelchairs – Part 8: Requirements and test methods for static, impact and fatigue strengths	Tested	Tested	Tested	S.E.
ISO 7176-9:2009 Wheelchairs – Part 9: Climatic tests for electric wheelchairs	Tested	Tested	Tested	S.E.
ISO 7176-10:2008 Wheelchairs – Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs	Tested	Tested	Tested	S.E.
ISO 7176-11:2012 Wheelchairs – Part 11: Test dummies	Tested	Tested	Tested	S.E.
ISO 7176-13:1989 Wheelchairs – Part 13: Determination of coefficient of friction of test surfaces	Tested	Tested	Tested	S.E.
ISO 7176-14 Wheelchairs – Part 14: Power and control systems for electrically powered wheelchairs and scooters – Requirements and test methods	Tested to current edition (2022)	Tested	Tested	S.E.
ISO 7176-15:1996 Wheelchairs – Part 15: Requirements for information disclosure, documentation and labelling	Tested to alternative state-of-the-art standards. See Note 11.	Tested	Tested	Note 1
ISO 7176-16:2012 Wheelchairs – Part 16: Resistance to	N/A	Tested	Tested	Note 2

ignition of postural support devices				
ISO 16840-10:2021 Wheelchair seating – Part 10: Resistance to ignition of postural support devices — Requirements and test method	Tested	N/A	N/A	Note 2

Notes to analyze the differences in non-clinical performance testing among the subject device, the predicate device and the reference device are summarized below.

- Note 1: In place of the wheelchair and scooter-specific standard ISO 7176-15:1996, the labeling of the subject device conforms to
 - ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer
 - ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements, and
 - EN 12184:2022 Electrically powered wheelchairs, scooters and their chargers – Requirements and test methods, Section 13 Information Supplied by the manufacturer

in alignment with the state-of-the-art in wheelchair and scooter development. Conformance to these standards ensures that the labeling of the subject device provides both the generic information concerning medical devices and the specific information relevant to powered scooters to users in an effective manner. The labeling of the subject device is considered substantially equivalent to that of the predicate device and does not raise concerns about safety or effectiveness.

- Note 2: In place of ISO 7176-16:2012 Wheelchairs – Part 16: Resistance to ignition of postural support devices, that was withdrawn on June 8, 2021, the subject device was tested to ISO 16840-10:2021 Wheelchair seating – Part 10: Resistance to ignition of postural support devices — Requirements and test method, which superseded ISO 7176-16:2012. Conformance to the current standard ensures that the subject device aligns with the state-of-the-art. The subject device’s resistance to ignition is considered substantially equivalent to that of the predicate device and does not raise concerns about safety or effectiveness.

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

Standard	Subject Device	Predicate Device	Reference Device	Result
ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	Tested	Tested	Tested	S.E.
ISO 10993-10:2021 Biological evaluation of medical devices – Part 10: Tests for skin sensitization	Tested to current edition (2021)	Tested	Tested to ISO 10993-10:2010 edition	S.E.
ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Tests for irritation	Tested	N/A	Tested to ISO 10993-10:2010 edition	S.E.

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 test samples were found to conform with the following test standards.

Table 3 Comparison of electrical safety and electromagnetic compatibility testing standards

Standard	Subject Device	Predicate Device	Reference Device	Result
ISO 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers	Tested	Tested	Tested	Equivalent
ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs	N/A	Tested	N/A	Equivalent Note 3 and Note 4
IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems	Tested	N/A	Tested	Equivalent Note 3
IEC 60335-2-29:2016+A1:2019 Safety of household and similar electrical appliances Part 2-29: Particular requirements for battery chargers	Tested	N/A	Tested	Equivalent Note 4
EN 60601-1-2:2015+A1:2021 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests	Tested	N/A	Tested	Equivalent Note 4
EN 61326-1 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements	Tested to current edition (2021)	N/A	Tested	Equivalent Note 4

Notes to analyze the differences in technological characteristics between the subject device and the predicate device are summarized below.

- Note 3: The subject device uses a lithium-ion battery while the predicate device uses a pair of lead-acid batteries. The ISO 7176-25 standard adopted by the predicate device is specific to lead acid batteries and lead acid battery chargers and is not applicable to the lithium-ion battery chemistry for the subject device.

The lithium-ion battery passed the safety testing per 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 – Part 2: Lithium systems.

In addition, the subject device passed the safety and performance testing per ISO 7176 standards. Lithium-ion battery is a proven technology that is widely used in medical devices and does not introduce new and intolerable safety risks. These test results demonstrate that the subject device, despite its difference in battery chemistry, has the same level of safety and effectiveness as the predicate device.

- Note 4: Although the chargers of the subject and predicate devices have different specifications to accommodate the difference in battery chemistry, the WHILL-proprietary lithium-ion battery charger manufactured by Delta Electronics was tested to rigorous safety standards—
 - IEC 60335-2-29:2016 Household and Similar Electrical Appliances - Safety - Part 2-29: Particular Requirements For Battery Chargers
 - EN 60601-1-2: 2015+A1:2021 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
 - EN 61326-1: 2021 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.

The ISO 7176-25 standard adopted by the predicate device is specific to lead acid batteries and lead acid battery chargers and is not applicable to the lithium-ion battery chemistry for the subject device. The subject device's lithium-ion battery charger is identical to that of the reference device WHILL Model F (K221438) and has been in distribution. The test results and the real-world evidence of the lithium-ion battery charger demonstrate the same level of safety and effectiveness as that of the predicate device.

Software Verification and Validation Testing

Software Verification and Validation Testing was conducted per the requirements of ANSI AAMI IEC 62304:2006/A1:2015.

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 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

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 R (Subject Device) described herein has an equivalent intended use and the same fundamental technology as the cleared primary predicate device, Innuovo W3331F (K222495), and the reference device, Powered Wheelchair WHILL Model F (K221438). Based on the analysis presented for the design differences between the subject device and primary predicate device, it can be concluded that the WHILL Model R is as safe and effective as, and substantially equivalent to the predicate device.

Element of Comparison	Subject Device WHILL Model R (3-wheel, 4-wheel)	Predicate Device Innuovo W3331F (K222495)	Remark
Manufacturer	WHILL, Inc.	Zhejiang Innuovo Rehabilitation Devices Co., Ltd	-
Common or Usual Name	Powered scooter	Powered scooter	Same
Product Code	INI	INI	Same
Product Classification	Class II	Class II	Same
Device Classification Name	Vehicle, Motorized 3-Wheeled	Vehicle, Motorized 3-Wheeled	Same
Regulation Number	21 CFR 890.3800	21 CFR 890.3800	Same
Indications for Use			
Indications for Use	The Model R is a motor-driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	Same
Type of Use	Over the counter (OTC)	Over the counter (OTC)	Same
Physical Characteristics			
Device weight including battery	3-wheel variant: 114.9 lbs. (52 kg) 4-wheel variant: 125 lbs. (56.7 kg)	107.2 lbs. (46.8 kg)	Equivalent Note 1
Device length	3-wheel variant: 43.7" (1,110 mm) 4-wheel variant: 44.0" (1,118 mm)	37.0" (940 mm)	Equivalent Note 1
Device width	21.3" to 35.1" (540 to 892 mm)	19.7" (500 mm)	Equivalent Note 1
Device Construction	Solid aluminum frame	Steel frame	Equivalent Note 2
Number of front wheels	3-wheel variant: 1 4-wheel variant: 2	1	Equivalent Note 3
Number of rear wheels	2	2	Same
Diameter of front wheel(s)	7.6"	7.4" (190 mm)	Similar
Diameter of rear wheels	10.4"	7.4" (190 mm)	Equivalent Note 1
Ground clearance	2" (50 mm)	1.77" (45 mm)	Equivalent Note 1
Battery pack	1 rechargeable lithium-ion battery Ratings: 25.3 V, 10.5Ah	2 rechargeable lead acid batteries in series Ratings: 12 V x 2 pcs, 12Ah	Different Note 4
Battery weight	6.0 lbs. (2.7 kg)	19.4 lbs. (8.8 kg)	Equivalent

			Note 1
Charger type	Off-board	Off-board	Same
Charger ratings	28.49 V _{DC} 2.4 A	24V _{DC} 2A	Equivalent Note 5
Battery charging time	~5 hours	Information not available	
Operating Characteristics			
Operating environments	Indoor and outdoor use excluding the following conditions -step sizes greater than 2" (5 cm) in height -slopes greater than 10° in gradient -gaps greater than 3.9" (10 cm) in width -soft surfaces such as sand, mud, snowy or frozen paths	Indoor use and restricted outdoor use on pavements or paved footpaths only	Equivalent Note 6
Maximum weight capacity	325 lbs. (147 kg)	264.55 lbs. (120 kg)	Equivalent Note 1
Maximum forward speed	5 mph (8 km/h)	3.73 mph (6 km/h)	Equivalent Note 1
Braking system	Electromagnetic	Electromagnetic	Same
Minimum braking distance from max speed	3 wheels model: 4.36' (1.33 m) 4 wheels model: 4.46' (1.36 m)	4.9' (1.5 m)	Equivalent Note 1
Turning radius	3-wheel variant: 36.2" (920 mm) 4-wheel variant: 38.2" (970 mm)	47.2" (1,200 mm)	Equivalent Note 1
Obstacle climbing height	2" (50 mm)	Information not available	
Drive system	2-wheel drive (rear wheel drive)	2-wheel drive (rear wheel drive)	Same
Dynamic stability on incline (Maximum allowable inclination)	10°	9°	Equivalent Note 1
Driving range on full battery charge	3-wheel variant: 10.69 mi (17.2 km) 4-wheel variant: 9.57 mi (15.4 km)	9.32 mi (15 km)	Equivalent Note 7
Design Features			
Motor rating	150 W x 2 pcs	24 V 180 W	Different Note 1
Motor controller	Manufacturer: WHILL Model: 22-21060-0	Information not available	

Distance between armrests	21.0", 23.0" or 25" (53.5, 58.5 or 63.5 cm)	17.3" to 22.0" (44 to 56 cm)	Equivalent Note 1
Armrest height	8.3" , 9.2" or 10.2" (210, 234 or 258mm)	Information not available	
Portability	Disassemble for transport	Disassemble for transport	Same

Notes to analyze the differences in technological characteristics between the subject device and the predicate device are summarized below.

- Note 1: Despite the differences in “device weight”, “device length”, “device width”, “ground clearance”, “turning radius”, “diameter of rear wheels”, “battery weight”, “maximum weight capacity”, “maximum forward speed”, “motor rating” and “distance between armrests”, both the subject device and the predicate device comply with
 - ISO 7176-1:2014 Wheelchairs – Part 1: Determination of static stability
 - ISO 7176-2 Wheelchairs – Part 2: Determination of dynamic stability of electrically powered wheelchairs, and
 - ISO 7176-5 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space,

ensuring that both devices share an equivalent level of static and dynamic stability and maneuverability therefore an equivalent level of safety and effectiveness.

- Note 2: Despite the difference in the material used in device construction, both the subject device and the predicate device comply with ISO 7176-8 Wheelchairs – Part 8: Requirements and test methods for static, impact and fatigue strengths ensuring that both devices share an equivalent level of durability therefore an equivalent level of safety and effectiveness.
- Note 3: The 3-wheel variant of the subject device shares the same approach to wheelbase design with the predicate device and is substantially equivalent. On the other hand, the 4-wheel variant of the subject device with its weight more evenly distributed across all 4 wheels is inherently more stable than 3-wheel powered scooters, therefore is safer and more effective by design. Both the 3-wheel and the 4-wheel variants of the subject device passed the same safety and performance testing on static and dynamic stability and maneuverability:
 - ISO 7176-1:2014 Wheelchairs – Part 1: Determination of static stability
 - ISO 7176-2 Wheelchairs – Part 2: Determination of dynamic stability of electrically powered wheelchairs, and
 - ISO 7176-5 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space

demonstrating that the 4-wheel variant does not raise concerns about safety or effectiveness.

- Note 4: The subject device uses a lithium-ion battery while the predicate device uses a pair of lead-acid batteries. The ISO 7176-25 standard adopted by the predicate device is specific to lead acid batteries and lead acid battery chargers and is not applicable to the lithium-ion battery chemistry for the subject device.

The lithium-ion battery used in the subject device has passed the safety testing per 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 – Part 2: Lithium systems.

In addition, the subject device passed the safety and performance testing per ISO 7176 standards. Lithium-ion batteries are a proven technology that is widely used in medical devices and does not introduce new and intolerable safety risks. These test results demonstrate that the subject device, despite its difference in battery chemistry, has the same level of safety and effectiveness as the predicate device.

- Note 5: Although the chargers of the subject and predicate devices have different specifications to accommodate the difference in battery chemistry, the WHILL-proprietary lithium-ion battery charger manufactured by Delta Electronics was tested to rigorous safety standards—
 - IEC 60335-2-29:2016 Household and Similar Electrical Appliances - Safety - Part 2-29: Particular Requirements For Battery Chargers
 - EN 60601-1-2: 2015+A1:2021 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
 - EN 61326-1: 2021 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.

The ISO 7176-25 standard adopted by the predicate device is specific to lead acid batteries and lead acid battery chargers and is not applicable to the lithium-ion battery chemistry for the subject device.

The subject device's lithium-ion battery charger is identical to that of the reference device WHILL Model F (K221438) and has been in distribution. The test results and the real-world evidence of the lithium-ion battery charger demonstrate the same level of safety and effectiveness as that of the predicate device.

- Note 6: The subject device's operating environments are based on specific limitations, while the predicate device is restrictive to pavements or paved footpaths without taking weather-dependent conditions into account. Nevertheless, both devices share the same indications for use and were tested to the same safety and performance standards:
 - ISO 7176-1:2014 Wheelchairs – Part 1: Determination of static stability
 - ISO 7176-2 Wheelchairs – Part 2: Determination of dynamic stability of electrically powered wheelchairs and
 - ISO 7176-5 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuvering space.

Based on these reasons, the differences in wording of the operating environments for the subject and predicate devices do not raise concerns about safety or effectiveness or impact the subject device's substantial equivalence to the predicate device.

- Note 7: The subject device's longer driving range improves usability, in comparison with that of the predicate device, and does not raise new concerns about safety or effectiveness.
- Note 8: Given that the subject device has demonstrated an equivalent level of static and dynamic stability, passing
 - ISO 7176-1:2014 Wheelchairs – Part 1: Determination of static stability and
 - ISO 7176-2 Wheelchairs – Part 2: Determination of dynamic stability of electrically powered wheelchairs,

The subject device is safer and more effective than the predicate device in terms of minimum braking distance from max speed, because a shorter braking distance allows the user to react quicker.

Element of Comparison	Subject Device WHILL Model R (3-wheel, 4-wheel)	Reference Device WHILL Model F (K221438)	Remark
Manufacturer	WHILL, Inc.	WHILL, Inc.	-
Common or Usual Name	Powered scooter	Powered wheelchair	Similar
Product Code	INI	ITI	Different Note 9
Product Classification	Class II	Class II	Same
Device Classification Name	Vehicle, Motorized 3-Wheeled	Wheelchair, powered	Different Note 9
Regulation Number	21 CFR 890.3800	21 CFR 890.3860	Different Note 9
Indications for Use			
Indications for Use	It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	The intended use of the Model F powered wheelchair is to provide outdoor and indoor mobility to person limited to a seated position that are capable of operating a powered wheelchair.	Different Note 9
Type of use	Over the counter (OTC)	Over the counter (OTC)	Same
Wireless Communication Characteristics			
Remote control	Bluetooth key fob: lock and unlock device Mobile app: -Display general device information (e.g. driving distance, battery capacity) -Power on/off control -Speed profile setting -Firmware update/patch	Bluetooth key fob: lock and unlock device Mobile app: -Display general device information (e.g. driving distance, battery capacity) -Power on/off control -Speed profile setting -Firmware update/patch -Remote driving	Equivalent Note 10
Type of wireless technology	IEEE 802.15.4 (Bluetooth Low Energy)	IEEE 802.15.4 (Bluetooth Low Energy)	Same
FCC compliance	CFR 47, Part 15	CFR 47, Part 15	Same
EMC compliance	ISO 7176-21:2009	ISO 7176-21:2009	Same
Wireless coexistence compliance	ANSI C63.27:2017	ANSI C63.27:2017	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	Same
Mobile app	iOS and Android	iOS and Android	Same

Wireless RF frequency range	2.402 GHz to 2.480 GHz	2.402 GHz to 2.480 GHz	Same
Wireless RF maximum output power	6 dBm	6 dBm	Same
Wireless operating range	10 m	10 m	Same

Notes to analyze the differences in technological characteristics between the subject device and the reference device are summarized below.

- Note 9: Although the subject device is a powered scooter, not a powered wheelchair like the reference device. The two devices share highly similar indications for use, intended for use by patients limited to a seated position. Both devices conform to the same set of recognized consensus standards on performance, safety and effectiveness. The subject device has wireless functionality to control the device with the same technological means as the reference device. Hence, both the subject and the reference devices are considered substantially equivalent concerning the aspects of wireless technology.
- Note 10: While the predicate device does not have any remote-control capabilities, the remote control features of the subject device are nearly identical to those of the reference device. The only difference is that the subject device does not have a remote driving feature like the reference device. All the features such as display general device information (e.g. driving distance, battery capacity), power on/off control, speed profile setting, firmware update/patch the subject device are equivalent to those of the reference device. Exclusion of the remote driving feature reduces the use-related risks and the security risks of the subject device. Furthermore, the subject device and the reference device share identical wireless communication characteristics, and their wireless features passed the same set of safety and performance testing. As such, the remote control and wireless communication features of the subject device do not raise concerns about safety or effectiveness.