June 12, 2026

Whill, Inc.
Tsuyoshi Iriyama
2-1-11, Higashi-Shinagawa
Shinagawa, Tokyo 1400002
Japan

Re: K261175
Trade/Device Name: WHILL (WHILL Model C2)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: April 10, 2026
Received: April 10, 2026

Dear Tsuyoshi Iriyama:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Tushar Bansal, PhD
Acting 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K2611175

Please provide the device trade name(s).

WHILL (WHILL Model C2)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

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

510(k) #:

510(k) Summary

Prepared on:

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	WHILL.Inc
Applicant Address	2-1-11 Higashi-Shinagawa, Shinagawa-Ku Tokyo, 140-0002, Japan
Applicant Contact Telephone	+81-70-4414-098
Applicant Contact	Mr. TSUYOSHI IRIYAMA
Applicant Contact Email	tsuyoshi.iriyama@whill.inc

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	WHILL (WHILL Model C2)
Common Name	Powered wheelchair
Classification Name	Wheelchair, Powered
Regulation Number	890.3860
Product Code(s)	ITI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K213383	WHILL Model C2	ITI

Device Description Summary

21 CFR 807.92(a)(4)

The subject device, the WHILL Model C2 series, incorporates the following modifications to the previously cleared WHILL Model C2 (K213383).

Major Design Change (Risk Level Impacting) from K213383

1. BLE Security Level Upgrade (Encryption Algorithm) to Mode:1/Level:3.
The Bluetooth Low Energy (BLE) security level has been upgraded, including implementation of an encryption algorithm, in accordance with IEC 81001-5-1.

For additional details, please refer to the Software/Firmware and Cybersecurity/Interoperability section.

Minor Design Changes (Addition of Accessories) from K213383

1. New Off-Board Lithium-Ion Battery charger

Model: ADP-69CR A (Color change of status indication LED from RED to Yellow)

2. New Rechargeable Lithium-Ion Battery Lineup

Standard Type: 23-15000-0 (272.4 Wh) H098-8S4P Note: Distance range: 16km

High-Capacity Type: 23-15002-0 (496 Wh) M043-7S4P Note: Distance range: 27.9km

3. New USB Type-C Off-Board Lithium-Ion Battery Charger

Model: A100d

4. Add accessories

24-10065-1 Model: Model C2 Backrest Mounting System

For further information, please refer to the EMC, Wireless, Electrical, Mechanical, and Thermal Safety sections, which include testing conducted with the Model C2 in combination with the above accessories. No additional risk regarding safety and effectiveness of the device.
Except for the design changes described above, the subject device is identical to the previously cleared WHILL Model C2 (K213383) in terms of intended use, fundamental scientific technology, and overall device design.

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 powered 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 C2, 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 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 (For safety reasons, Joystick control takes priority over 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 12miles (20km) with a maximum speed limit of up to 5mph (8km/h).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same.

Technological Comparison

21 CFR 807.92(a)(6)

Substantial Equivalence Analysis

Predicate Device

510(K) Number	Manufacturer	Device Name	Product Code
K213383	WHILL, Inc	WHILL Model C2	ITI

Comparison with Predicate Device

Table 1 Comparison of subject device with predicate device (K213383)

Element of Comparison	**Subject Device WHILL Model C2 (K261175)**	**Predicate Device WHILL Model C2 (K213383)**	**Remark**
Manufacturer	WHILL, Inc.	WHILL, Inc.	-
Common or Usual Name	Powered Wheelchair	Powered Wheelchair	Same
Product Code	ITI	ITI	Same
Product Classification	Class II	Class II	Same
Device Classification Name	Powered Wheelchair	Powered Wheelchair	Same
Regulation Number	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 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.	Same
Type of Use	Over the counter (OTC)	Over the counter (OTC)	Same
Physical Characteristics			
Device weight including battery	116.4 lbs (52.8 kg)	116.4 lbs (52.8 kg)	Same
Device length	38.8”	38.8”	Same
Device width	21.8” to 25.6”	21.8” to 25.6”	Same
Device Height	26.4” to 28.7”	26.4” to 28.7”	Same
Device Construction	Solid aluminum frame	Steel frame	Same
Number of front wheels	2	2	Same
Number of rear wheels	2	2	Same
Diameter of front wheel(s)	10.11”	10.11”	Same

Diameter of rear wheels	10.4”	10.4”	Same
Ground clearance	3”	3”	Same
Battery pack	1 rechargeable lithium-ion battery 1.23-00006-0, 7S4PMH1: Ratings: 25.3 V, 10.5Ah 2.23-15000-0, H098-8S4P Ratings: 25.6 V, 10.6Ah 3.23-15002-0, M043-7S4P Ratings: 25.83 V, 19.2Ah	1 rechargeable lithium-ion battery 1.23-00006-0, 7S4PMH1: Ratings: 25.3 V, 10.5Ah	SE-Note 1
Battery weight	1. 23-00006-0, 7S4PMH1: 6.0 lbs. 2. 23-15000-0, H098-8S4P: 6.6 lbs 3. 23-15002-0, M043-7S4P: 6.9 lbs	23-00006-0: 6.0 lbs.	SE-Note 1
Charger type	Off-board	Off-board	SE-Note 1
Charger ratings	1. ADP-69BR/CR Series: 28.49 V_{DC} / 2.4 A 2. A100d: 5V/3.0A 9V/3.0A 12V/3.0A 15V/3.0A 20V/5.0A	1.ADP-69BR Series: 28.49 V_{DC} / 2.4 A	SE-Note 2
Charger Port Type	1. ADP-69BR/CR Series: XLR Type Connector 2. A100d: USB Type-C	1. ADP-69BR Series: XLR Type Connector	SE-Note 2
Status Indication LED Color	1. ADP-BR A 2. ADP-CR A 3. A100d Charging: 1.2.3: Green blinking Full charge: 1.2.3: Solid Green Power On/Standby: 1.: Solid RED 2.3: Solid Yellow Safety Protection: 1.: RED blinking 2.: Yellow blinking 3.: Solid RED	1. ADP-BR A Charging: 1: Green blinking Full charge: 1: Solid Green Power On/Standby: 1: Solid RED Safety Protection: 1: RED blinking	SE-Note 2
Battery charging time	1. 23-00006-0, 7S4PMH1: ~5hours. 2. 23-15000-0, H098-8S4P: ~4.5hours 3. 23-15002-0, M043-7S4P: ~ 9hours	1. 23-00006-0, 7S4PMH1: ~5hours.	SE-Note 1
Operating Characteristics			
Operating environments	Indoor and outdoor use	Indoor and outdoor use	Same

Maximum weight capacity	300lb(136kg)	300lb(136kg)	Same
Maximum forward speed	5 mph (8 km/h)	5 mph (8 km/h)	Same
Braking system	Electromagnetic	Electromagnetic	Same
Turning radius	30”	30”	Same
Obstacle climbing height	2”	2”	Same
Drive system	2 Wheel Drive (Rear Wheel Drive)	2 Wheel Drive (Rear Wheel Drive)	Same
Dynamic stability on incline (Maximum allowable inclination)	10°	10°	Same
Driving range on full battery charge	1. 23-00006-0, 7S4PMH1: 19.2km 2. 23-15000-0, H098-8S4P: 16km 3. 23-15002-0, M043-7S4P: 27.9km	1. 23-00006-0, 7S4PMH1: 19.2km	Same
Design Features			
Motor rating	150 W x 2 pcs	150 W x 2 pcs	Same
Motor controller	Manufacturer: WHILL Model: 21-00011-0	Manufacturer: WHILL Model: 21-00011-0	Same
Portability	Disassemble for transport	Disassemble for transport	Same
Joystick Location	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.	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.	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.	Same
Seat Width	16”, 18” and 20”	16”, 18” and 20”	Same
Back support Height	13.4 – 18.1”	13.4 – 18.1”	Same
Adjustable Backrest Mounting System	Prepared	None	SE-Note 3
Disassembly	Users can disassemble model C2 without using tools into four components: Seat, Front Drive Base, Rear Drive Base, and Battery.	Users can disassemble model C2 without using tools into four components: Seat, Front Drive Base, Rear Drive Base, and Battery.	Same
Wireless Communication Characteristics			
Remote control	Bluetooth key fob: lock and unlock device	Bluetooth key fob: lock and unlock device	Same

	Mobile app: -Display general device information (e.g. driving distance, battery capacity) -Power on/off control -Speed profile setting -Firmware update/patch -Remote control	Mobile app: -Display general device information (e.g. driving distance, battery capacity) -Power on/off control -Speed profile setting -Firmware update/patch -Remote control	
Type of wireless technology	IEEE 802.15.4 (Bluetooth Low Energy)	IEEE 802.15.4 (Bluetooth Low Energy)	Same
FCC compliance	47 CFR, Part 15	47 CFR, Part 15	Same
EMC compliance	ISO 7176-21:2009	ISO 7176-21:2009	Same
Wireless coexistence compliance	ANSI C63.27:2017 (EN 12184)	ANSI C63.27:2017 (EN 12184)	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
BLE Security Mode Level	Mode: 1, Level: 3	Mode: 0, Level:1	SE-Note 4

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

The subject device is identical technological characteristics as the predicate device in terms of principle of operation, portability design and construction and the drive and braking systems. The differences in technological characteristics may be summarized in 2 major categories

1. Ad-hoc Accessories of Li-ion Batteries, Charger, Adjustable backrest mounting system
2. BLE security level

[Note1] Ad-hoc accessories of Li-ion Battery

The subject device added two types of new lithium-ion battery. 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.

The subject device with ad-hoc accessories passed the safety and performance testing per ISO 7176 standards (Table 3). 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 has the same level of safety and effectiveness as the predicate device.

[Note2] Ad-hoc accessories of Charger
Although the chargers of the subject and predicate devices have different specifications, indication LED color, and connector type, the WHILL-proprietary lithium-ion battery charger manufactured 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

[Note 3] Ad-hoc accessories of adjustable backrest mounting system
The subject device with ad-hoc accessories passed the safety and performance testing per ISO 7176 standards (Table 3).
[Note 4] BLE security level
-Predicate device: BLE security Level: Mode 0 / Level 1
-Subject device: BLE security Level: Mode 1 / Level 3

BLE Security level is upgraded from the predicate device. For this change, the subject device of security level is much improved than the predicate device. However, regarding the level of safety and effectiveness are substantially equivalent as the predicate device.

Summary of Technical Characteristics of Device Compared to Predicate Device

The subject device is designed to fulfill the requirements of the following recognized consensus standards:

Non-clinical performance testing

Table 2 Comparison of non-clinical performance testing standards

Standard	Subject Device	Predicate Device	Result
ISO 7176-1:2014 Wheelchairs – Part 1: Determination of static stability	Yes	Yes	Same

ISO 7176-2:2017 Wheelchairs – Part 2: Determination of dynamic stability of electrically powered wheelchairs	Yes	Yes	Same
ISO 7176-3:2012 Wheelchairs – Part 3: Determination of effectiveness of brakes	Yes	Yes	Same
ISO 7176-4:2008 Wheelchairs – Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range	Yes	Yes	Same
ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass and manoeuvring space	Yes	Yes	Same
ISO 7176-6:2018 Wheelchairs – Part 6: Determination of maximum speed of electrically powered wheelchairs	Yes	Yes	Same
ISO 7176-7:1998 Wheelchairs – Part 7: Measurement of seating and wheel dimensions	Yes	Yes	Same
ISO 7176-8:2014 Wheelchairs – Part 8: Requirements and test methods for static, impact and fatigue strengths	Yes	Yes	Same
ISO 7176-9:2009 Wheelchairs – Part 9: Climatic tests for electric wheelchairs	Yes	Yes	Same
ISO 7176-10:2008 Wheelchairs – Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs	Yes	Yes	Same
ISO 7176-11:2012 Wheelchairs – Part 11: Test dummies	Yes	Yes	Same
ISO 7176-13:1989 Wheelchairs – Part 13: Determination of coefficient of friction of test surfaces	Yes	Yes	Same
ISO 7176-14: 2022 Wheelchairs – Part 14: Power and control systems for electrically powered wheelchairs and scooters — Requirements and test methods	Yes	Yes	Same
ISO 7176-15:1996 Wheelchairs – Part 15: Requirements for information disclosure, documentation and labelling	Yes, alternative state-of-the-art standards. See SE-Note 12.	Yes	Same
ISO 7176-16:2012 Wheelchairs – Part 16: Resistance to ignition of postural support devices	Yes	Yes	Same SE-Note 13.

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

- Note 12: 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 13: WHILL-manufactured specialty cushion that tested to ISO 8191-1/8191-2 that is equivalent to ISO 7176-16.

Electrical Safety and Electromagnetic Compatibility Testing

Table 3 Comparison of electrical safety and electromagnetic compatibility testing standards

Standard	Subject Device	Predicate 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	Yes	Yes	Same
ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs	N/A	N/A	Same
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	Yes	Yes	Same

IEC 60335-2-29:2016+A1:2019 Safety of household and similar electrical appliances Part 2-29: Particular requirements for battery chargers	Yes	Yes	Same
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	Yes	Yes	Same

Biocompatibility Testing

The biocompatibility testing for the subject device was conducted according to EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Table 4 Comparison of biocompatibility testing standards

Standard	Subject Device	Predicate Device	Result
ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	Yes	Yes	Same
ISO 10993-10:2021 Biological evaluation of medical devices – Part 10: Tests for skin sensitization	Yes	Yes	Same
ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Tests for irritation	Yes	Yes	Same

Software Verification Testing

Software verification testing was performed to evaluate the functionality of the subject device's design and operational principles. Software verification testing was conducted, and the documentation level was determined on the subject device as recommended by the FDA's guidance document "FDA Guidance: Content of Premarket Submissions for Device Software Functions." Software verification testing conforms to IEC 62304:2006/Amd1:2015 Medical Device Software – Software Life Cycle.

FCC Radio Frequency Testing

The radiofrequency wireless function of the subject device was tested to FCC requirements and found to comply with 47 CFR 15.249.

Wireless Coexistence 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.

Conclusion on 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, WHILL Model C2 (K213383). Based on the performance data presented for the design differences between the subject device and the predicate device, it can be concluded that the WHILL Model C2 is as safe and effective as, and substantially equivalent to, the predicate device. Hence the subject and the predicate device are considered substantially equivalent concerning the aspects of wireless technology.

The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed devices identified in this submission. Thus, the subject device is substantially equivalent to the predicate device.