July 14, 2026

Jochu Technology Co., Ltd.
Jimmy(Chihming) Wei
President
42, Kuangfu Rd., Hsin Chu Industrial Park,
Hukou Hsin Chu, Taiwan (R.O.C.)
Hsin Chu,
Taiwan

Re: K261232
Trade/Device Name: IERO Mobility Scooter (IERO-01)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: April 14, 2026
Received: April 15, 2026

Dear Jimmy(Chihming) Wei:

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,

Digitally signed by MARY S. KESZLER -S
Date: 2026.07.14 11:43:19 -04'00'

for Tushar Bansal, PhD
Acting Assistant Director
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

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.	K261232

Please provide the device trade name(s).

IERO Mobility Scooter (IERO-01)

Please provide your Indications for Use below.

This device is intended for medical purposes to provide mobility to persons restricted to a seated position.

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) Summary - K261232

I. SUBMITTER

Device Submitter:
JOCHU technology CO., LTD.
No. 42, Guangfu Rd., Hukou Township, Hsinchu County 303036, Taiwan (R.O.C.)

Phone: 886 – 3 – 5981919 - 1600
Fax: 886 – 3 – 5983600

Contact Person: JIMMY(CHIHMING) WEI
Date Prepared: December 22, 2025

II. DEVICE

Name of Device: IERO Mobility Scooter
Common or Usual Name: Electrical scooter
Classification Name: Motorized three-wheeled vehicle.
Regulatory Class: II
Product Code: INI

III. PREDICATE DEVICE

KARMA Scooter KS-747.2, K041677
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Device design and function：The IERO Mobility scooter does not have any novel features since it is a mobility device, designed for adults who are restricted to a seated position but still have normal eyesight and hearing, and are physically and mentally capable of operating an electric mobility device and has similar specifications to other similar devices on the market, such as appearance and performance.

material used：Most structure made by steel with powder coating. Seat fabric, back fabric used by Knitted Fabrics.

physical properties：L1360mm/W625mm/H1066 mm, Total weight 110KG, Batteries (lead-acid), Speed 11.5 km/h, Min. braking distance 2.5m, Rated slope 12°, Max. climbable obstacle height 80 mm.

The associated accessories include:

- Seat belts
- Cushion
- Back Cushion
- Batteries and chargers

V. INDICATIONS FOR USE

This device is intended for medical purposes to provide mobility to persons restricted to a seated position.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Mobility Scooter is intended for medical purposes to provide mobility to persons restricted to a seated position. The subject and predicate devices are based on the following same technological elements:

- Principle of operation
- Charging Device
- Batteries
- Duration of contact
- Sterilization method

The following technological differences exist between the subject and predicate devices:

- overall dimension
- weight
- Speed
- Drive range
- water resistant

The major differences existing of the two Mobility Scooters are the different overall dimension, weight and Speed between the two devices. The differences are not safety aspect. So the new device is substantially equivalent to the predicate device in this aspect.

- Substantial Equivalence Comparison Table

	New device	**Predicate device**	
K number	K261232	K041677	
Manufacturer	Jochu Technology Co., Ltd.	Karma Medical Products CO., LTD.	
Brand and Product Items	IERO Mobility scooter IERO-01	Karma Scooter KS-747.2	
Classification	Class II	Class II	
Device picture			
1. Overall description of the device design (Technical Characteristics)			**Comparison** (Same/Similar/Different)
Indications for Use	This device is intended for medical purposes to provide mobility to persons restricted to a seated position.	This device is intended for medical purposes to provide mobility to persons restricted to a seated position.	Same

Principle of operation	Revolves around converting electrical energy from rechargeable batteries into mechanical motion through a motor and drive mechanism. The user controls the scooter's speed and direction using throttle controls and steering mechanisms, while safety features, braking systems, and battery management contribute to a secure and efficient mobility experience.	The movement of the Scooter is controlled by the rider who uses hand controls locals at the top of the steering column. The device can be disassembled for transport and is provided with an onboard battery charger.	Same
Speed	11.5 km/h	15 km/h	Similar to the predicate device. Minor deviation due to commercial consideration which would not affect the safety and performance (supported by testing conducted in accordance with **ISO 7176-4,6**).

Drive range	11.5 km/h: 26 km	15 km/h: 42 km	Similar to the predicate device. Minor deviation due to commercial consideration which would not affect the safety and performance (supported by testing conducted in accordance with **ISO 7176-4**).
Maximum Load	Maximum payload: 150 kg	Maximum payload: 135 kg	Similar to the predicate device. Minor deviation due to commercial consideration which would not affect the safety and performance (supported by testing conducted in accordance with **ISO 7176-5**).
Seat Dimensions	Width: 460 mm Depth: 457.2 mm Height: 660 mm	Width: 430 mm Depth: 435 mm Height: 610 ~ 635 mm	Similar to the predicate device. Minor deviation due to commercial consideration which would not affect the safety and performance (supported by testing conducted in accordance with **ISO 7176-5 and ISO 7176-7**).

Minimum Braking distance	Speed (11.5 km/h): 2600 mm	Speed (15 km/h): 3500 mm	Similar to the predicate device. Minor deviation due to commercial consideration which would not affect the safety and performance (supported by testing conducted in accordance with **ISO 7176-3 and ISO 7176-6**).
The new device and the predicate device have minor differences in speed, drive range, maximum load, seat dimensions, and minimum braking distance. However, these differences do not affect the performance and safety of the new device. The performance of the new device has been verified through safety and performance testing, the details are as follows: -Speed, drive range, maximum load, seat dimensions, and minimum braking distance: please refer to the testing conducted in accordance with **ISO 7176-4, ISO 7176-5, ISO 7176-6, and ISO 7176-7.**			Substantially Equivalent: **Yes**
2. Materials (Biology Characteristics)			**Comparison** (Same/Similar/ Different)
For similar kind and duration of contact	Contact the surface of body / long term (> 30 days)	Contact the surface of body / long term (> 30 days)	Same
Sterilization method	Non-sterile	Non-sterile	Same
Single use/ reusable	Reusable	Reusable	Same
Cleanability/ Infection Control	IPX4	This product is not guaranteed to be water resistant.	Different. This difference would not affect the safety and

			performance (supported by testing conducted in accordance with **ISO 7176-9**).
Biocompatibility and chemical characteristics	Conduct biocompatibility evaluation according to ISO 10993-1:2018, ISO 10993-5: 2009, ISO 10993-10: 2021, and ISO 10993-23:2021.	N/A	Predicate devices do not reveal their biocompatibility information. The safety regarding biocompatibility and chemical characteristics is supported by the biocompatibility evaluation conducted in accordance with **ISO 10993-1, ISO 10993-5, ISO 10993-10, and ISO 10993-23.**
The predicate device does not provide biocompatibility information. However, the subject device is intended for use with clothing and involves long-term contact. Safety with respect to biocompatibility and chemical characteristics is supported by the biocompatibility evaluation reports conducted in accordance with ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021, and ISO 10993-23:2021. Based on these evaluations, the subject device is considered as safe and as effective as the predicate device.			Substantially Equivalent: **Yes**
3.Energy sources			**Comparison** (Same/Similar/ Different)
Charging Device	Output current :6 A ± 8 % Output voltage: 24 V nominal	Output current :6 A Output voltage: 24 VDC	Same (supported by testing conducted in accordance with **IEC 60601-1-2 and ISO 7176-14**).
Batteries	2 x 12 V/50 Ah leak proof/AGM	2 x 12 V/50 Ah leak proof/AGM	Same (supported by testing conducted in accordance with **ISO 7176-14**).

The energy sources of the new device and the predicate device are the same. The electrical safety and electromagnetic compatibility of the new device can be supported by the testing, the details are as follows: - Charging and batteries: please refer to the testing conducted in accordance with **IEC 60601-1-2.**			Substantially Equivalent: **Yes**
4. Other key technological features			**Comparison** (Same/Similar/ Different)
software features	PG,S-Drive S120A motor controller firmware	N/A	Predicate devices do not reveal their software information. The safety regarding software are supported by the evaluation of EN62304 Gap Analysis
clinical purpose	This device is intended for medical purposes to provide mobility to persons restricted to a seated position.	This device is intended for medical purposes to provide mobility to persons restricted to a seated position.	Same
Software verification and validation Report and **EN62304 Gap Analysis.** The clinical purpose of the predicate device - "Karma Scooter KS-747.2" is consistent with the clinical purpose of the new device. According to MDCG 2020-5 Clinical Evaluation - Equivalence published by the European Commission, similar relevant critical performance in view of the expected clinical effect for a specific intended purpose is acceptable.			Substantially Equivalent: **Yes**
Summary Scientific justification of similar but not the same features in the safety and clinical performance of the devices are as below: 1. Charging and batteries: please refer to the testing conducted in accordance with **ISO 7176-14,21.** 2. Speed, drive range, maximum load, and seat dimensions: please refer to the testing conducted in accordance with **ISO 7176-4, 5, 6, 7.**			

3. Biocompatibility and chemical characteristics: please refer to biocompatibility evaluation report of **10993-1:2018, ISO 10993-5: 2009 and ISO 10993-10: 2021**, biocompatibility evaluation report. 4. Clinical purpose: • Karma Scooter KS-747.2 Instruction for use: https://www.karmamedical.com/featured_item/ks-747-2/ • IERO Mobility scooter Instruction for use: The differences between the new device and the predicate device are minor deviations that would not affect the safety and performance of the device. For some technical parameters, and speed and the biocompatibility and chemical characteristic consideration, the predicate device did not reveal the relevant information. However, according to the performance test report and biocompatibility evaluation report of ISO 10993-1:2018, 10993-5: 2009, ISO 10993-10: 2021 and ISO 10993-23:2021, the subject device is believed to be as safe and as effective as the predicate device under its clinical condition. Therefore, there are no significant differences in the safety and performance between the subject device and the predicate device.	

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Testing Summary Table

#	Test Standard	Test standard	Result
Biocompatibility testing			
1	In vitro cytotoxicity	ISO 10993-5:2009	Pass
2	Intracutaneous Irritation Study in White Rabbits	ISO 10993-23:2021/Amd 1:2025	Pass
3	Guinea Pig Skin Sensitization Study	ISO 10993-10:2021	Pass
Electrical safety and electromagnetic compatibility			
1	Wheelchairs – Part 14: Power and control systems for electrically powered wheelchairs and scooters — Requirements and test methods	ISO 7176-14:2008	Pass
2	Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters	ISO 7176-21:2009	Pass
Software Verification and Validation Testing			
1	Medical device software — Software life cycle processes	IEC 62304:2006	Pass
Safety and Performance Testing			
1	Wheelchairs – Part 1: Determination of static stability	ISO 7176-1:2014	Pass
2	Wheelchairs – Part 2: Determination of dynamic stability of electrically powered wheelchairs	ISO 7176-2:2017	Pass
3	Wheelchairs – Part 3: Determination of effectiveness of brakes	ISO 7176-3:2012	Pass
4	Wheelchairs – Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range	ISO 7176-4:2008	Pass
5	Wheelchairs – Part 5: Determination of dimensions, mass, and maneuvering space	ISO 7176-5:2008	Pass
6	Wheelchairs – Part 6: Determination of maximum speed of electrically powered wheelchairs	ISO 7176-6:2018	Pass
7	Wheelchairs – Part 7: Measurement of seating and wheel dimensions	ISO 7176-7:1998	Pass
8	Wheelchairs – Part 8: Requirements and test methods for static, impact and	ISO 7176-8:2014	Pass

	fatigue strengths		
9	Wheelchairs – Part 9: Climatic tests for electric wheelchairs	ISO 7176-9:2009	Pass
10	Wheelchairs – Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs	ISO 7176-10:2008	Pass
11	Wheelchairs – Part 11: Test dummies	ISO 7176-11:2012	Pass
12	Wheelchairs – Part 13: Determination of coefficient of friction of test surfaces	ISO 7176-13:1989	Pass
13	Wheelchairs – Part 15: Requirements for information disclosure, documentation, and labelling	ISO 7176-15:1996	Pass
14	ISO 16840-10:2021 Wheelchair seating —Part 10: Resistance to ignition of postural support devices — Requirements and test method	ISO 16840-10:2021	Pass

A. Biocompatibility testing

The safety regarding biocompatibility and chemical characteristics are supported by the biocompatibility evaluation report of ISO 10993-1:2018, ISO 10993-5: 2009, ISO 10993-10: 2021, and ISO 10993-23:2021.

Biocompatibility testing:

●ISO 10993-1:2018

●ISO 10993-5:2009
Knitted Fabrics,
PU Foam,

●ISO 10993-10:2021
Knitted Fabrics,
PU Foam, Report

●ISO 10993-23:2021
Knitted Fabrics,
PU Foam,

B. Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the IERO Mobility Scooter. The system complies with ISO 7176-14:2008 and ISO 7176-21:2009 for EMC.

C. Software Verification and Validation Testing

Software verification and validation testing were conducted per IEC 62304:2006 and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Minor" level of concern, the risk of this software has been assessed as level A, so there is no risk that is not within the scope under normal circumstances.

D. Safety and Performance Testing

The safety and performance of the device per ISO 7176-1:2014, ISO 7176-2:2017, ISO 7176-3:2012, ISO 7176-4:2008, ISO 7176-5:2008, ISO 7176-6:2018, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-9:2009, ISO 7176-10:2008, ISO 7176-11:2012, ISO 7176-13:1989, and ISO 7176-15:1996, ISO 16840-10:2021. The device has passed all the criteria.

E. Medical Device Recalls

There are no significant serious adverse events that occurred.

VIII. CONCLUSIONS

The differences between the new device and the predicate device are minor deviations that would not affect the safety and performance of the device. For some technical parameters, and speed and the biocompatibility and chemical characteristic consideration, the predicate device did not reveal the relevant information. However, according to the performance test report and biocompatibility evaluation report of ISO 10993-1:2018, 10993-5: 2009, ISO 10993-10: 2021, and ISO 10993-23:2021 the subject device is believed to be as safe and as effective as the predicate device under its clinical condition. Therefore, there are no significant differences in the safety and performance between the subject device and the predicate device.