June 8, 2026

Jiangsu Intco Medical Products Co., Ltd.
% Doris Chen
Regulatory Affairs Specialist
Shanghai Jiushun Enterprise Management Tech Service Co., Ltd
Room 1502, BaoAn Buiding, No.800 Dongfang Road
Shanghai, 200122
China

Re: K253257
Trade/Device Name: Virgo Mobility Scooter (Virgo-D, Virgo-F)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: May 8, 2026
Received: May 8, 2026

Dear Doris Chen:

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

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.	K253257

Please provide the device trade name(s).

Virgo Mobility Scooter (Virgo-D,Virgo-F)

Please provide your Indications for Use below.

The intended use of this device is to provide mobility to persons limited to a seated position that have the capability of operating a scooter.

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

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

510(k) Summary

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

The assigned 510(k) Number: K253257

Summary Prepared Date: 6/05/2026

1. Applicant :

- Sponsor Name: JIANGSU INTCO MEDICAL PRODUCTS CO., LTD.
- Address: No. 298 Yandunshan Road, Zhenjiang New District 212132 Jiangsu P.R. China.
- Contact Person (including title): Shiqun Liu (Manager)
- Phone: +86-511-83174088
- E-mail: liushiqun@intco.com

3 Submission Correspondent:

- Contact Person: Doris Chen
- Shanghai Jiushun Enterprise Management Technology Service Co., Ltd.
- Address: Room 1502,BaoAn Buiding,No.800 Dongfang Road,Shanghai,China.
- Tel: +86-21-50931939
- Email: doris-chen@isosh.com

4 Subject Device Information:

- Type of 510(k) submission: Traditional
- Trade Name: Virgo Mobility Scooter
- Models: Virgo-D, Virgo-F
- Common Name: Scooter
- Classification Name: vehicle, motorized 3-wheeled
- Review Panel: Physical Medicine
- Product Code: INI
- Regulation Number:21CFR 890.3800
- Regulation Class: II

5 Predicate Device Information:

- Sponsor: Heartway Medical Products Co., Ltd.
- Common Name: POWERED SCOOTER
- Trade Name:Auto Folding Scooter
- 510(k) number: K220227
- Review Panel: Physical Medicine
- Product Code: INI
- Regulation Number:21 CFR 890.3800
- Regulation Class: II

2. Device Description

The Virgo Mobility Scooter (Model: Virgo-D, Virgo-F) is an indoor and outdoor use electrical scooter that is battery operated. It has a base with steel frame, two front wheels, two rear wheels, two anti-tip wheels, a seat, a handle bar to control the driving function, a steering column, a control panel, an electric motor, an electromagnetic brake, a rechargeable battery with an off-board charger, a back-rest and 2 armrests. The Virgo Mobility Scooter is foldable, which makes it very compact to store or transport. The difference between the two models is that Virgo-D is separable and Virgo-F is one-piece. The movement of the electrical scooter is controlled by the rider who uses speed control lever to control the direction and speed of an electrical scooter. The motor power is 270W. The device uses a Dynamic 50A electronic controller. The device is provided with an off-board battery charger (Input: AC100-240V, Output: DC 24V, 2 A). The maximum weight capacity of Virgo Mobility Scooter is 299.8 lbs (136 kg), and its maximum forward speed is 5.0 mph (8 km/h).The dimensions of (Length * Width *Height) the device before and after folded are shown in the table below.

Model	Unfolded (Length * Width * Height)	Folded (Length * Width * Height)
Virgo-D	1045mm x 485mm x 880mm	1045mm x 485mm x 350mm
Virgo-F	1045mm x 485mm x 880mm	1045mm x 485mm x 350mm

3. Indications for Use

The intended use of this device is to provide mobility to persons limited to a seated position that have the capability of operating a scooter.

4. Comparison with predicate device

The Virgo Mobility Scooter has the same technological characteristics and fundamental design as the predicate device. The Virgo Mobility Scooter and the predicate device are designed to provide mobility to persons restricted to a sitting position. The Virgo Mobility Scooter has equivalent Indications for Use as the predicate device. The differences between subject device and predicate device do not raise any new questions of safety or effectiveness.

Table 1 General Comparison

Elements of Comparison	**Subject Device**	**Predicate Device**	**Verdict**
Manufacturer	JIANGSU INTCO MEDICAL PRODUCTS CO., LTD.	Heartway Medical Products Co., Ltd.	--
K Number	K253257	K220227	--
Product Code	INI	INI	Same
Regulation Number	21 CFR 890.3800	21 CFR 890.3800	Same
Device Trade Name	Virgo Mobility Scooter	Auto Folding Scooter	--
Model	Virgo-D, Virgo-F	S21F	--
Indications for Use	The intended use of this device is to provide mobility to persons limited to a seated position that have the capability of operating a scooter.	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	Similar
User	Adults	Adults	Same
Number of Wheels	4	4	Same
Frame Type	Steel	Fixed / Aluminum alloy	Different
Rear Wheels	Size:7.5”x2.5” Type: Pu Solid Tire x 2	Size:8” x 2” Type: PU solid tire x 2	Different
Front wheels	Size:7.5”x2.5” Type: Pu Solid Tire x 2	Size:7” x 1.6” Type: PU solid tire x 2	Different
Brake System	Electromagnetic brake	Not publicly available	
Upholstery inflammability	Pass	Pass	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
testing			
Overall Dimensions (L*W*H)	Virgo-D (1045mm x 485mm x 880mm) Virgo-F (1045mm x 485mm x 880mm)	840 mm x 460 mm x 770mm	Different
Design style	Foldable	Foldable	Same
Drive System	Rear wheel drive	Not publicly available	
Weight Capacity	299.8lbs (136kg)	253 lbs. (115 kg)	Different
Max Speed	5.0 mph (8.0 km/h)	3.75 mph (6 km/h)	Different
Battery Rating	One 24V DC, 15Ah Lead-acid Battery	One 25.2 Vdc, 11.5 Ah Lithium-ion Battery	Different
Charger Type	Off-board external type Model:HP0060W(B)-M Input:100-240 VAC, 50-60Hz, 1.2-0.5A Output: 24VDC , 2.0A	Off-board external type Model: NL07C-25HT Input: 110-240 Vac, 50/60Hz, 84 W Output: 29.05 Vdc, 2.5 A	Different
Cruise Range	9.9 miles (16 km)	9.3 miles (15 km)	Different
Patient-contacting parts and materials	Handlebar: PU Seat (cushion & backrest): PVC artificial leather	Handlebar: TPU Seat cushion: PU Foam Seat & backrest leather: Vinyl Fabric	Different
Controller Type	Dynamic, R series, DR50	Dynamic, R series, DR50	Same
Motor Type	3.0 A max, 24 Vdc , 270 W	2.5 A max, 24 Vdc, 180 W	Different
Scooter Weight	with Battery Virgo-D(99.2lbs/45Kg) Virgo-F(99.2lbs/45Kg) without Battery Virgo-D(76lbs/34.5Kg) Virgo-F(76lbs/34.5Kg)	with Battery 51.8 lbs. (23.5 kg) without Battery 46.9 lbs. (21.3 kg)	Different
Suspension	None	None	Same
Turning Radius	51.18”/ 1300mm	43.7” / 1110 mm	Different
Static / Dynamic Stabilities(Degrees)	10/6	6/3	Different
Ground Clearance	Virgo-D:1.18” (30mm) Virgo-F:1.18” (30mm)	1.18” (30 mm)	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
Kerb Climbing Ability	1.8”(45 mm)	0.59” (15 mm)	Different
Performance Test	Comply with ISO 7176 series	Comply with ISO 7176 series & RESNA WC-1 series, RESNA WC-2 series	Similar
Biocompatibility			
Cytotoxicity	Under the conditions of the study, the device is noncytotoxic.	Under the conditions of the study, the device is noncytotoxic.	Same
Sensitization	Under the conditions of the study, the device is nonsensitizing.	Under the conditions of the study, the device is nonsensitizing.	Same
Irritation	Under the conditions of the study, the device is nonirritating. (Intracutaneous Irritation Test)	Under the conditions of the study, the device is nonirritating. (Skin Irritation Test)	Similar

COMPARISON DISCUSSION

Both devices are classified as Vehicle, Motorized 3-Wheeled per 21 CFR 890.3800 under product code INI. The indications for use for both devices are the same. Both devices, Virgo Mobility Scooter and Auto Folding Scooter, use the same scooter technologies.

Frame Type

The frame materials of the two devices are different. The subject device uses a steel frame and the predicate device use an aluminum alloy frame. The subject device has passed the requirements of ISO 7176 series standards. It is demonstrated there are no new safety and effectiveness concerns raised by the frame material differences for the subject device.

Dimensions

The dimensions of the two devices are different. Unfolded dimensions for the subject device are 1045mm x 485mm x 880mm (Virgo-D & Virgo-F). Unfolded dimensions for the predicate device are 840 mm x 460 mm x 770mm, and the differences between two devices are so small and are validated by the compliance testing of ISO 7176 serial standard on the subject device. It is demonstrated there are no new safety and effectiveness concerns raised by the unfolded dimensional differences for the subject device.

Wheel size

Front wheel size are different for the two devices, which are 7.5” x 2.5” (190 x 63.5 mm) for subject device and 7” x 1.6” (177.8 x 40.64 mm) for predicate device . As seen from the data, the differences for the front wheel size and type are small. These differences will not raise any new safety and effectiveness concerns for the subject device.

Weight Capacity

The maximum loading of the subject device is 299.8lbs (136kg) and it is 253 lbs (115 kg) for the predicate device. The maximum loading of the subject device is larger than the predicate device. There are no new safety and effectiveness concerns due to the difference of the maximum loading for the subject device.

Max Speed

The maximum speed for the subject device is 5.0 mph (8.0 km/h)and the predicate device has maximum speed of 3.75mph(6.0 km/h).The difference of the max speed between the two devices is small and there are no new safety and effectiveness concerns raised by the difference of the max speed for the subject device.

Battery Rating

The battery ratings for both devices are different. The subject device used sealed lead-acid battery rating at 24 Vdc, 15 Ah, and the predicate device used one Lithium-ion battery rating at 25.2 Vdc, 11.5 Ah. The AGM battery for the subject device has passed the requirements of ISO 7176-14:2008, so there are no new safety and effectiveness concerns raised by subject device.

Charger Type

The battery chargers for the predicate and subject devices are different, but the battery charger for the subject device passes the EMC standard: IEC 60601-1-2:2014. There are no new safety and effectiveness concerns raised by using different battery charger for the subject device.

Cruise Range

The cruise ranges for the predicate and the subject devices are 9.9 miles and 9.3 miles.

The cruise range of subject device is more than the predicate device. The

difference of the cruise ranges will not raise any new safety and effectiveness concerns for the subject device.

Patient-contacting parts and materials

The patient-contacting parts and materials are different for both devices. But, the patient-contacting parts of the subject device passed biocompatibility testing per ISO 10993-5:2009, ISO 10993-10:2021, and ISO 10993-23:2021. The differences between them do not raise any new safety and effectiveness concerns for the subject device.

Motor Type

The motor types for both devices are different. The subject device uses motor of 270W/ 24 Vdc/ 3.0 A , and the predicate device uses motor of 180 W /24 Vdc / 2.5 A. But the motor used in the subject device passed the requirements of the EMC standards: IEC 60601-1-2：2014, and performance standards: ISO 7176-14:2008. So, there are no new safety and effectiveness concerns raised due to different motor used by the subject devices.

Scooter Weight

The scooter weight for both devices are different. The scooter weight with battery for the Virgo-D and Virgo-F are 99.2lbs (45Kg). The scooter weight with battery for predicate device with battery weighs 51.8 lbs. There are no new safety and effectiveness concerns raised by the different scooter weights.

Turning Radius

The turning radius for the predicate device is 43.7” and it is 51.18” for the subject device. The turning radius is related to the size of the scooter. The dimensions of the subject device is larger than the predicate device, so the turning radius of the subject device is also larger than the predicate device. There are no new safety and effectiveness concerns raised by the differences in turning radius.

Static/Dynamic Stabilities

The static/dynamic stabilities for the subject device are 10/6 degrees, which are higher than the predicate device 6/3 degrees.. Therefore, there are no new safety and effectiveness concerns raised by the different static/dynamic stabilities for the subject device.

Kerb Climbin Ability

Maximum obstacle climbing for two devices is 1.8”(45 mm) for subject device and 0.59” (15 mm) for predicate device. Subject device has larger obstacle climbing. There are no new safety and effectiveness concerns raised by the difference of the maximum obstacle climbing for the subject device.

Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 7176-1:2014 Wheelchairs – Part 1: Determination of staticstability.

ISO 7176-2:2017 Wheelchairs – Part 2: Determination of dynamic stability of electric wheelchairs

ISO 7176-3:2012 Wheelchairs – Part 3: Determination of effectiveness of brakes.

ISO 7176-4:2008 Wheelchairs – Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range

ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass and manoeuvring space.

ISO 7176-6:2018 Wheelchairs – Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs

ISO 7176-7:1998 Wheelchairs – Part 7: Measurement of seating and wheel dimensions.

ISO 7176-8:2014 Wheelchairs – Part 8: Requirements and test methods for static, impact and fatigue strengths.

ISO 7176-9:2009 Wheelchairs – Part 9: Climatic tests for electric wheelchairs

ISO 7176-10:2008 Wheelchairs – Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs

ISO 7176-11:2012 Wheelchairs – Part 11: Test dummies.

ISO 7176-13:1989 Wheelchairs – Part 13: Determination of coefficient of friction of test surfaces

ISO 7176-14:2008 Wheelchairs – Part 14: Power and control systems for electrically powered wheelchairs and scooters – Requirements and test method.

ISO 7176-15:1996 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling

IS0 16840-10:2021 Wheelchair seating - Part 10: Resistance to ignition of postural support devices requirements and test method.

ISO 7176-21:2009 Wheelchairs Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers

ISO 7176-22:2014 Wheelchairs – Part 22: Set-up procedures

ISO 7176-25:2013 Wheelchairs – Part 25: Batteries and chargers for powered wheelchairs IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2:2014 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance --Collateral Standard: Electromagnetic disturbances --Requirements and tests.

AIM 7351731 Rev 3.00 2021--Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

ISO 10993-5: 2009, Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity.

ISO 10993-10:2021 Biological evaluation of medical devices -- Part 10: Tests for skin sensitization.

ISO 10993-23:2021, Biological evaluation of medical devices -- Part 23: Tests for irritation

Biocompatibility testing

Biocompatibility of the Virgo Mobility Scooter was evaluated in accordance with the FDA guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The following tests were performed:

Cytotoxicity (ISO 10993-5:2009)

Intracutaneous irritation (ISO 10993-23:2021)

Sensitization (ISO 10993-10:2021)

Patient-contacting Parts	**Material**	**Direct or Indirect contact / Contact classification & contact duration**	**Tests conducted**	**Conclusion**
Seat cushion/Back cushion	PVC	Direct-contact / Surface contact/Intact skin/ Repeated use for a duration of several hours per day,over a period of up to 5 Years (long-term >30 days)	Cytotoxicity Sensitization Intracutaneous Irritation tests	Pass
Handle bar/Armrest	PU	Direct-contact / Surface contact/ Intact skin/ Repeated use for a duration of several hours per day,over a period of up to 5 Years (long-term >30 days)	Cytotoxicity Sensitization Intracutaneous Irritation tests	Pass
Dashboard complete set	PA6+GF30/ ABS	Direct-contact / Surface contact/ Intact skin/ Repeated use for a duration of several hours per day,over a period of up to 5 Years (long-term >30 days)	Cytotoxicity Sensitization Intracutaneous Irritation tests	Pass

Note:(1) PVC【polyvinyl chloride】; (2) PU【polyurethane】; (3)PA6+GF30【PA6+GF30 is a 30% glass fibre reinforced polyamide】/ABS【Acrylonitrile-butadiene-styrene】

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Virgo Mobility Scooter . The scooter complies with the IEC 60601-1, IEC 60601-1-2 and the AIM 7351731 for EMC.

Clinical Testing

Based on the similarities of the device specifications, intended use, indications for use between the Virgo Mobility Scooter and its predicate device, no clinical studies were needed to support this 510(k) Premarket Notification.

5. Conclusion

The Virgo Mobility Scooter is substantially equivalent to the predicate device. The non-clinical testing demonstrates that the subject device is as safe, as effective and performs as well as the predicate device, Auto Folding Scooter (K220227).