October 12, 2022

Heartway Medical Products Co., Ltd.
% Ke-Min Jen
Contact Person
Roc Chinese-European Industrial Research Society
No. 58, Fu Chiun Street
Hsin Chu City, Taiwan 30067
Taiwan

Re: K220227
Trade/Device Name: Auto Folding Scooter, S21F
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: September 6, 2022
Received: September 14, 2022

Dear Ke-Min Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220227

Device Name
Auto Folding Scooter, S21F

Indications for Use *(Describe)*
The device is intended for medical purposes to provide mobility to persons restricted to a sitting 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 510(k) number: K220227

Submitter's Name:	**HEARTWAY Medical Products Co., Ltd.** No.18, Jingke Central 1st Rd., Nantun Dist., Taichung City, Taiwan, R.O.C. 40852
Date summary prepared:	October 12, 2022
Proprietary Name:	HEARTWAY Auto Folding Scooter, S21F
Common or Usual Name:	POWERED SCOOTER
Classification Name	Vehicle, Motorized 3- Wheeled (Class II, 21 CFR 890.3800)
Product Code:	INI
Official Correspondent:	Dr. KE-MIN JEN (email: ceirs.jen@msa.hinet.net) TEL: 886-3-5208829
Predicate Device:	Heartway Medical Products Co., Ltd. Power Mobility Scooter, Brio S19 K150987

- **Indications for Use:**

  The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

- **Description of the device:**

  The Auto Folding Scooter S21F is designed for indoor use for adults with mobility restrictions. It is classified as Class II medical device per US FDA 21 CFR 890.3800. It is compact, maneuverable and not necessarily able to overcome obstacles. The maximum load is 115 kg.

  The product is not intended for visually impaired people. The drivers need to be mentally and physically suitable to drive the scooters. The fingers need to work functionally. The driving distance will be reduced if the scooter is used frequently on slopes, rough ground or climbing curb. The scooter is not for use as a seat in motor vehicle.

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Auto Folding Scooter S21F is battery powered and configured with four solid wheels (03) (08), a seat (04), a handle bar to control the driving function (01), a cross bar (05), a main frame (06), a foot-rest (02), a back-rest (04), a set of 2 anti-tippers (09), referred to the components and parts diagrams of S21F below.

S21F is driven by two solid rear wheels (08) as the drive wheel, two solid front castors (03) as the steering wheel, using the steering handles (01) to control the front frame assembly (02) to control the front wheels (03) as the power scooter steering direction mechanism. Steering handles (01) is able to control driving forward, driving backward, speed control. The main frame (06) is equipped with a rear bumper to allow the scooter to sustain an impact without damage to the power scooter safety system. The maximum loading weight of S21F is 253 lbs. (115 kg), and its maximum speed is 3.75 mph (6 km/h). The dimensions of (Length * Width *Height) of the unfolded device are 33.0" x 18.1" x 30.3" (840 mm x 460 mm x 770 mm) and 28.7" x 17.3" x 16.5" (730 mm * 440 mm * 420 mm) for the folded device. The weight of the device is 51.8 lbs. (23.5 kg) with battery and 46.9 lbs. (21.3 kg) without battery. Seat belt is a standard accessory to S21F power scooter, and is not a 510(k)-clearance accessory. It can be installed onto the seat (as seen in the diagram below) by consulting with the local authorized dealer for seat belt installation.

Seat belt of S21F

The static stability results of tilt over tests performed laterally, posteriorly and anteriorly with a user of maximum allowable weight 253 lbs. and a fixed seat height 14.8" (376 mm) are **3** degrees for three cases.

There are no any external wired and /or wireless communication interfaces which may impact the cybersecurity information of our subject device. The following surfaces are recommended NOT to operate on:

- Sand surface
- Wet or icy surface
- Road maintenance hole metal cover
- Avoid going up multiple steps.

- Avoid using escalators. Use the elevator.
- Too steep incline over 3 degrees.
- Ground clearance to battery: 1.18" (30 mm)
- Curb climbing ability: 0.59" (15 mm)

EMC & Electrical Safety Testing and Performance Bench Testing are conducted per the following standards:

- **EMC standards (**applied for S21F & Charger)
  - **ISO 7176-21:2009** Wheelchairs – Part 21: Requirements and test method for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
  - **RESNA WC-2:2019 Section 21: 2009** Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters

- **Electrical Safety standards** (applied for battery chargers: METCO, NL07C-25HT)
  - ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment-Part 1: General requirements for basic safety and essential performance

- **Scooter safety performance standards applied for S21F**
  - **ISO 7176-1, -3, -5, -7, -8, 15, -22 series** & RESNA WC-1 series
  - **ISO 7176-2, -4, -6, -9, -10** series & RESNA WC-2 series
  - **ISO 7176-11, ISO 7176-13**
  - **ISO 7176-14:2008** Wheelchairs -- Part 14: Power and control systems for electrically powered wheelchairs and scooters -- Requirements and test methods
  - **RESNA WC-2 Section 14:2009 –** Power and control systems for electrically powered wheelchair and scooters – Requirements and test method**s**
  - **ISO 7176-16:2012** Resistance to Ignition of Postural Support Devices Test

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- **Biocompatibility information**

Patient-contacting parts	Materials	Testing standards	Testing laboratory	Verdict	Attached files
Dial set & Handle bar	DIOSHY® TPU (Thermoplastic Urethane)	*ISO 10993-5:2009 *in vitro* Cytotoxicity test	*Super Laboratory Co., Ltd.	Pass	VOL_015_003
		*ISO 10993-10:2010 Maximization Sensitization test	*Super Laboratory Co., Ltd.	Pass	VOL_015_004
		*ISO 10993-10:2010 Skin Irritation test	*Super Laboratory Co., Ltd.	Pass	VOL_015_005
Seat cushion	PU Foam	*ISO 10993-5:2009 *in vitro* Cytotoxicity test	*SGS Taiwan Ltd. Ultra Trace & Industrial Safety Hygiene	Pass	VOL_015_006
		*ISO 10993-10:2010 Maximization Sensitization test	*SGS Mechanical & Hardgoods Lab	Pass	VOL_015_007
		*ISO 10993-10:2010 Skin Irritation test	*SGS Mechanical & Hardgoods Lab	Pass	VOL_015_008
Seat leather Seat belt	Vinyl Fabric	*ISO 10993-5:2009 *in vitro* Cytotoxicity test	*SGS Mechanical & Hardgoods Lab	Pass	VOL_015_009
		*ISO 10993-10:2010 Maximization Sensitization test	*SGS Mechanical & Hardgoods Lab	Pass	VOL-015_010
		*ISO 10993-10:2010 Skin Irritation test	*SGS Mechanical & Hardgoods Lab	Pass	VOL_015_011

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- **Comparison table**

Comparison Item	Predicate device	Subject (New) Device	Verdict
Manufacturer	Heartway medical products Co., Ltd.	Heartway Medical Products Co., Ltd.	--
Trade Name	Power mobility scooter	Auto Folding Scooter	--
Model Name	Brio S19	S21F	--
510(K) Number	K150987	To Be Assigned	--
Indications for Use	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	Same
Number of Wheels	4	4	Same
Anti-Tipper	One set of 2 anti-tippers	One set of 2 anti-tippers	Same
Frame Type	Fixed / Aluminum alloy	Fixed / Aluminum alloy	Same
Biocompatibility testing	Iso 10993-1:2009 Iso 10993-5:2009 Iso 10993-10:2010	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010	Same
Rear Wheels Size Type	 8” x 2” Pu Solid Tire x 2	 8” x 2” PU solid tire x 2	Same
Front Castor Size Type	 7” x 1.6” Pu Solid Tire x 2	 7” x 1.6” PU solid tire x 2	Same
Armrest type	NA	NA	Same
Wheel Lock type	Push-to- lock	Push-to- Lock	Same
Upholstery inflammability testing	Pass	Pass	Same
Overall Dimensions Length Width Height	 36.6” (930 mm) 19.0” (485 mm) 37.2” (945 mm)	 33.0” (840 mm) 18.1” (460 mm) 30.3” (770 mm)	Different
Folded Dimensions (L x W x H)	36.6” x 19” x 13.3” (930 x 485 x 340) mm	28.7” x 17.3” x 16.5” (730 x 440 x 420) mm	Different
Weight Capacity	220 lbs. (100 kg)	253 lbs. (115 kg)	Different
Max Speed	5.0 mph (8.0 km/h)	3.75 mph (6 km/h)	Different
Battery Rating	Two 12 Vdc, 12 Ah Sealed lead acid Batteries	One 25.2 Vdc, 11.5 Ah Lithium-ion Battery	Different

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Charger Type	Off-board external type CTE 4C24050A Input: 110 -240 Vac, 50 Hz, 2 A Output: 24 Vdc, 5 A	Off -board external type METCO, NL07C-25HT Input: 110-240 Vac, 50/60 Hz, 84 W Output: 29.05 Vdc, 2.5 A	Different
Cruise Range	11.25 miles (18 km)	9.3 miles (15 km)	Different
Patient- contacting parts and materials	Seat -PVC material Hand grip - PVC material Safety belt - PVC material	Dial set / Handle bar: TPU Seat cushion: PU Foam Seat & backrest leather: Vinyl Fabric	Different
Controller Type	Penny & Giles S-drive	Dynamic, R series, DR50	Different
Motor Type	3A, 24 Vdc / 270 W	2.5 A max, 24 Vdc, 180 W	Different
Scooter Weight: with Battery without Battery	 69 lbs. (31.3 Kg) 53 lbs. (24.0 Kg)	 51.8 lbs. (23.5 kg) 46.9 lbs. (21.3 kg)	Different
Suspension	Cross brace	None	Different
Turning Radius	32.2” (820 mm)	43.7” / 1110 mm	Different
Static / Dynamic Stabilities (Degrees)	10 /6	6 / 3	Different
Ground Clearance	2.3” (60 mm)	1.18” (30 mm)	Different
Kerb Climbing Ability	1.7” (45 mm)	0.59” (15 mm)	Different
Warranty	3 years: main frame 1 year: controller /gear motor /batteries Without exhaustive and wear parts	2 years: Main frame 1.5 years: Controller 1 year: Charger Without exhaustive and wear parts	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, Brio S19 and S21F, use the same scooter technologies.

The overall dimensions of the subject device are smaller than those of the predicate device. Both devices, Brio S19 and S21F, are designed to function as small-scale motorized 3-wheeled vehicles, so their overall dimensions and weight capacities are small and similar, and their differences are not large. The subject device S21F meets the performance requirements of ISO 7176 series, ISO 7176-14-2008: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test method, and RESNA WC-2 Sec 14: Power and control systems for electrically powered wheelchairs and scooters- Requirements and test methods. There are no any new safety and effectiveness concerns raised by the S21F due to the minor differences of the **overall dimensions** and **weight capacity**.

The **folded dimensions** of both devices are different, and the length and width of S21F while folded are smaller than Brio S 19 and height of the S21F while folded is larger than the Brio S19. We fold the scooter when transported, and smaller length and width need less space of the motor vehicle to store the scooter, and this brings out more convenience for the patient. There are no any new safety and effectiveness concerns raised by S21F due to the smaller volume or space of S21F.

The **maximum speed** for the subject device is 3.75 mph and the predicate device has maximum speed of 5.0 mph. Regarding the subject device has a slower maximum speed, it has higher dynamic stability performance than the predicate device. So, there are no any new safety and effectiveness concerns raised by the subject device S21F.

The **battery ratings** for both devices are different. The predicate device used two sealed lead acid batteries rating at 12 Vdc, 12 Ah, and the subject device used one Lithium -ion battery rating at 25.2 Vdc, 11.5 Ah. The Lithium-ion battery for the subject device has passed the requirements of ISO 7176-14:2008 and RESNA WC-2 Sec 14, so there are no any new safety and effectiveness concerns raised by S21F.

Because the subject device uses a new type battery: Lithium-ion battery, the **battery charger** is also adapted to use the METCO Lithium-ion battery charger NL07-25HT. The battery chargers for the predicate and subject devices are different, but the battery charger for the subject device passes the EMC standard: ISO 7176-21:2009, and Electrical Safety standard: ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012. There are no any new safety and effectiveness concerns raised by using different battery charger for the subject device S21F.

The **cruise ranges** for the predicate and the subject devices are 11.25 miles and 9.3 miles. The cruise range of S21F is less than the predicate device, and this difference relates with the frequency of battery charging and how far the patient will get to. The difference of the cruise ranges will not raise any new safety and effectiveness concerns for the subject device.

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 and ISO 10993-10:2010, the differences between them are not to raise any new safety and effectiveness concerns for the subject device.

The **electronic controllers** used by two devices are different. The Dynamic R-series DR50 controller used with the subject device S21F passed the ISO 7176-14:2008 and RESNA WC-2 Sec 14:2009. There are no any new safety and effectiveness concerns raised by the S21F due to using different electronic controllers.

The **motor types** for both devices are different. The predicate device uses motor of 270 W / 24 Vdc / 3A, and the subject 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: ISO 7176-21:2009, RESNA WC-2 Sec 21:2009, and performance standards: ISO 7176-14:2008, and RESNA WC-2 Sec 14:.2009. So, there are no any new safety and effectiveness concerns raised due to different motor used by the subject devices.

With the advancement of battery technology, S21F now uses one Lithium-ion battery, instead of using two Sealed Lead Acid batteries. The **weight** of one Lithium-ion battery is only 4.9 lbs. and the total weight of two Sealed Lead Acid batteries is 16 lbs. So, the scooter weight with battery for the S21F is 51.8 lbs. and the predicate device with battery weighs 69 lbs. There are no any new safety and effectiveness concerns raised by the different scooter weights.

There is a **suspension system** for the predicate device and no suspension for the subject device. The suspension used by the predicate device is installed to decrease the impact from ground to the patient, since the maximum speed of the subject device is 3.75 mph, which is less than the predicate device of 5 mph; there is no need to install suspension system on the S21F to reduce the impact to the scooter. Without suspension system for the subject device will let the patient feel more impact from the ground, but this is not related with the safety and effectiveness.

The **turning radius** for the predicate device is 32.2" and it is 43.7" for the subject device. A smaller turning radius will let the scooter move in a smaller space. But this is not related to the safety and effectiveness.

The **static/dynamic stabilities** for the subject device are 6/3 degrees, which are lower than the predicate device 10/6 degrees. We place the safety notice in the user manual to inform the users of these limitations – not to use the device on the slope angle greater than 3 degrees or not to use it outdoors. We install a set of anti-tippers on the back of the S21F to prevent the tipping on the slope. By doing these actions, there are no any new safety and effectiveness concerns raised by S21F due to the smaller stabilities of the subject device.

The **ground clearance** for the predicate device is 2.3" and it is 1.18" for the subject device. So, there are more limitations for the subject device than the predicate device when moving across an obstruct. But the purpose of the limitations is to let the patient know the capability of the subject device. A smaller clearance will not lead to the dangerous situations, instead it will prevent the patient from the potential harms.

The **kerb climbing ability** for the predicate device is 1.7" and it is 0.59" for the subject device. A smaller kerb climbing ability will not lead to dangerous situations, but it will bring about more cautions and more safety.

The **warranty** for the subject device is similar to the predicate device. The different warranty contents will result to the different costs paid by the customers, which is not related to the safety and effectiveness concerns. There are no any new safety and effectiveness concerns raised by the subject device due to the different warranty contents.

At last, the subject device passes the EMC testing per ANSI/RESNA WC-2:2009 Section 21 & ISO 7176-21:2009, and the performance testing per ISO 7176-14:2008 and RESNA WC-2 Section 14. The overall performances of the subject device are ensured.

- **CLINICAL INFORMATION**

  Not Applicable

- **CONCLUSIONS**

The subject device, HEARTWAY Auto Folding Scooter, S21F, is as safe and effective as, and functions in a manner equivalent to the predicate device, HEARTWAY Power Mobility Scooter, Brio S19 (K150987). 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 device identified in the submission. Thus, the subject device is substantially equivalent to the predicate device.