May 8, 2025

SunTech UK Ltd.
Jinfeng Ning
Official Correspondent
25 Ormside Way, Holmethorpe Industrial Estate
Rehill, Surrey RH1 2LW
United Kingdom

Re: K243110
Trade/Device Name: eFOLDi Navigator Powerchair (STPC-A)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: May 2, 2025
Received: May 2, 2025

Dear Jinfeng Ning:

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

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

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

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

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

Sincerely,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243110

Device Name

eFOLDi Navigator Powerchair (STPC-A)

Indications for Use *(Describe)*

The "eFOLDi Navigator Powerchair STPC-A" is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

K243110

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

1.0 Submitter Information

SunTech UK Ltd.
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Redhill, Surrey, RH1 2LW, UK
Tel： (44)-0-203 143 5168
Submitter's FDA Registration Number：N/A

Submission Correspondent

Jinfeng Ning
Manton Business and Technology Services
37 Winding Ridge, Oakland, NJ 07436
Tel: 608-217-9358
Email: jfning@gmail.com

Date of Summary: September 27, 2024

2.0 Device Information

Proprietary Name:	eFOLDi Navigator Powerchair STPC-A
Common Name:	Electric Wheelchair
Classification Name:	Powered Wheelchair
Device Classification:	II
Regulation Number:	21 CFR 890.3860
Product Code:	ITI
Panel:	Physical Medicine

3.0 Predicate Device Information:

Manufacturer:	Ningbo Baichen Medical Devices Co., Ltd.
Product Name:	Power Wheelchair (Model: BC-EA8000)
510(K) #:	K232121

4.0 Device description:

The eFOLDi Navigator Powerchair STPC-A is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position. The wheelchair has two front wheels, two rear wheels, two electric motors with electromagnetic brake, and one rechargeable Lithium-Ion batteries with an off-board charger. The movement of the wheelchair is controlled by the joystick controller or attendant control. When attendant control is in use, the wheelchair no longer responds to the joystick controller. The device is installed with an electromagnetic brake that will engage automatically when the wheelchair is not in use and the brake cannot be used manually. The wheelchair only can be operated on the flat road for both outdoor and indoor use, hospital, senior center, family or similar circumstances use only. The Powerchair only can be operated on the flat road or slopes less than 6 degrees. The Powerchair is foldable.

The Powerchair has a physical dimension of 108 (depth) x 59 (width) x 89 (height) cm, with the seat itself has a dimension of 35 (depth) x 45 (width) x 50 (height) cm. The footrest is 10 cm in height. The Powerchair is foldable, and the folded dimension is 34 (Long) x 59 (width) x 89 (height) cm.

The device has a weight capacity of 120 kilograms, and weighs 14 kilograms with battery (12 kilograms without battery). The color is black.

The Powerchair consists of four wheels, a magnesium alloy mechanical main frame, seat, handle, and 100% polyester flame retardant cloth for upholstery that is ignition resistant.

The Powerchair uses solid Polyurethane wheels and the front wheel has a diameter of 20 cm (8 inch) and the back wheel has a diameter of 30 cm (11.5 inch). Both front wheel and back wheels use solid tires.

The Powerchair has two motors of 24V and 180 Watt, which allows a maximum speed of 5.6 kilometers per hour, and maximum travel range of 13 kilometers. It brakes in the form of electromagnetic force to apply mechanical resistance to the back wheels to force stop.

The wheelchair is equipped with anti-tipper device.

5.0 Indications for Use:

The eFOLDi Navigator Powerchair STPC-A is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

6.0 Comparison to Predicate Devices

The "eFOLDi Scooter, Lite" manufactured by *"SUNTECH UK LTD"* is compared with the following Predicate Device in terms of intended use, design, material, specifications, and performance.

(1) K232121, "Power Wheelchair (Model:BC-EA8000)", manufactured by *"Ningbo Baichen Medical Devices Co., Ltd."*

The following table shows similarities and differences of use, design, and material between our devices and the predicate device.

Table 6.1: Comparison of Intended Use, Design, and Material

Characteristic	Subject Device	Predicate Device (K232121)	Substantial Equivalence
Indication for use	It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	S.E.
Operating surface & environment	Indoor and outdoor use	Indoor and outdoor use	S.E.
Number of wheels	4, including two front wheels and two rear wheels	4, including two front wheels and two rear wheels	S.E
Movement control method	By Joystick control and attendant control	By Joystick control	Similar
Drive Style (e.g., rear, mid, front)	Rear-wheel drive	Rear-wheel drive	S.E.
Brake system	Automatic electromagnetic brake system	Automatic electromagnetic brake system	S.E.
Braking distance	≤ 1.5 m	≤ 1.5 m	S.E.
Maximum safe operational incline degree	6°	6°	S.E.
Armrest	PVC leather foam	PU	Different
Battery charger	Off-board charger, input: 100-240V~1.8A,50/60Hz. Output: 29.4Vdc,2.0 A	Off-board charger input: 100-240V, 50/60Hz, 1.5A. Output: 24Vdc, 2A	Similar
Main frame material	Magnesium alloy	Aluminum Alloy	Similar
Back cushion	Polyester fabric	Polyester fabric	S.E.
Seat cushion	Polyester fabric	Rubber patch cloth and Oxford fabric	S.E.

Overall Dimensions (length*width*height)	1080 x 590 x 890 mm	950 x 625 x 930 mm	Similar
Folded Dimensions (length*width*height)	340 x 590 x 890 mm	775 x 440 x 410 mm	Similar
Front wheel size / type	8″ / PU Solid tire	5.9″x1.90″ / PU Solid tire	Similar
Rear wheel size / type	11.5″ / PU Solid tire	10.6″x1.97″ / PU Solid tire	Similar
Max speed Forward	5.6 km/h	Up to 6 km/h	S.E.
Max speed backword	Less than 3Km/h(0.78m/s)	Less than 3km/h(0.5m/s)	Similar
Max loading weight	120Kg (≈264.5lbs)	100Kg (≈220lbs)	Similar
Batteries	Rechargeable Li-ion battery:24VDC, 10Ah, 240Wh	Lithium 24V 6Ah	Different
Motor	Brushless DC motor; 24VDC; 180W, 2pcs	Brushless DC motor; 24VDC; 150W, 2pcs	Similar
Turning Radius	600mm	900mm	Similar
Maximum obstacle climbing	50mm	40mm	Similar

The minor differences between the subject device and predicate device do not raise any concerns in terms of safety and effectiveness.

7.0 Non-Clinical Study Summary

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

Tests	Standard
Biocompatibility	All user directly contacting materials are compliance with ISO10993-1 requirements

Performance	ISO 7176-1: Wheelchairs – Part 1: Determination of static stability ISO 7176-2: Wheelchairs - Part 2:Determination of dynamic stability of electrically powered wheelchairs ISO 7176-3: Wheelchairs - Part 3: Determination of effectiveness of brakes ISO 7176-4: Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range ISO 7176-5: Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space ISO 7176-6: Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs ISO 7176-7: Wheelchairs - Part 7: Measurement of seating and wheel dimensions ISO 7176-8: Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths ISO 7176-9: Wheelchairs - Part 9: Climatic tests for electric wheelchairs ISO 7176-10: Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs ISO 7176-11 Second edition 2012-12-01 Wheelchairs - Part 11: Test dummies ISO 7176-14: Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods ISO 16840-10: 2021 Wheelchair seating –Part 10: Resistance to ignition of postural support device – Requirements and test methods IEC 62133-2: Specifies requirements and tests for the safe operation of portable sealed secondary lithium cells and batteries containing non-acid electrolyte, under intended use and reasonably foreseeable misuse.

8.0 Clinical Study Summary

Clinical study is not performed for this product.

9.0 Conclusion

The conclusions drawn from the nonclinical tests that demonstrate is that the subject device is as safe, as effective, and performs as well as or better than the legally marketed device.