February 22, 2023

SunTech UK Ltd.
% Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K223492
Trade/Device Name: eFOLDi Scooter, Lite
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: January 12, 2023
Received: February 13, 2023

Dear Charles Shen:

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,

Julia E. Slocomb -S

Julia E. Slocomb -S
2023.02.22 13:36:19
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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)*
K223492

Device Name
eFOLDi Scooter, Lite

Indications for Use *(Describe)*
The "eFOLDI Scooter, Lite" 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.

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510(K) Number: K223492

510(k) Summary

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.
25 Ormside Way, Holmethorpe Industrial Estate,
Redhill, Surrey, RH1 2LW, UK
Tel：(44)-0-203 143 5168
Submitter's FDA Registration Number: N/A

Submission Correspondent

Charles Shen
Manton Business and Technology Services
37 Winding Ridge, Oakland, NJ 07436
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: November 16, 2022

2.0 Device Information

Proprietary Name:	eFOLDi Scooter, Lite
Common Name:	Electric Scooter
Classification Name:	Vehicle, Motorized 3-Wheeled
Device Classification:	II
Regulation Number:	21 CFR 890.3800
Product Code:	INI
Panel:	Physical Medicine

3.0 Predicate Device Information:

Manufacturer:	Nanjing Jin Bai He Medical Apparatus Co., Ltd.
Product Name:	Scooter (Model: FDB01)
510(K) #:	K201196

4.0 Device description:

The eFoldi Scooter, Lite is an indoor/outdoor electric scooter that is intended to be used by individuals that are able to walk but suffer from mobility limitations. It has a base with metal alloy frame, one front wheels, two rear wheels, a seat, an adjustable steering column, a tiller console, an electric motor, an electromagnetic brake, 2 rechargeable Lithium-Ion Battery with an off-board charger. The movement of the scooter is controlled by the rider who operates the throttle lever, speed control handle on the tiller console. The device is installed with an electromagnetic brake that will engage automatically when the scooter is not in use and the brake cannot be used manually. The Scooter only can be operated on the flat road or slopes less than 6 degrees. The scooter is foldable.

The scooter has a physical dimension of 117 (depth) x 55 (width) x 95 (height) cm, with the seat itself has a dimension of 36 (depth) x 36 (width) x 50 (height) cm. The footrest is 10 cm in height. The scooter is foldable, and the folded dimension is 65 (Long) x 55 (width) x 37 (height) cm.

The device has a weight capacity of 120 kilograms, and weighs about17 kilograms with battery (15 kilograms without battery). The color is dark grey.

The scooter consists of three wheels, a mechanical main frame, seat, handle, and Polyurethane artificial leather upholstery that is ignition resistant.

The frame of the scooter is made of magnesium alloy.

The scooter uses aluminum alloy wheels and has a diameter of 25.4 cm (10 inch) and the front wheel has a diameter of 20.3 cm (8 inch). Both front wheels use solid tires and the back wheel is pneumatic tire.

The scooter has a motor of 24V and 180 Watt, which allows a maximum speed of 6 kilometers per hour, and maximum travel range of 15 kilometers. It brakes by electromagnetic effect on the front wheel.

The wheel lock is in the form of electromagnetic force to apply mechanical resistance to the front wheels to force stop.

5.0 Indications for Use:

The “eFOLDI Scooter, Lite” 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) K201196, "Scooter (Model: FDB01)", manufactured by *"Nanjing Jin Bai He Medical Apparatus Co., Ltd*."

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

Table5.1: Comparison of Intended Use, Design, and Material

Characteristic	Subject Device	Predicate Device (K201196)	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.
Overall Dimensions	1170 x 550 x 950 mm	1050 x 550 x 870 mm	Similar
Folded Dimensions	370 x 550 x 670 mm	480 x 550 x 790 mm	Similar
Weight with batteries	16.7 KG	29 KG	Similar
Weight without batteries	15 KG	24.2 KG	Similar
Controller	MM32SPIN05X from Mindmotion	British PG Controller PG45A	Different
Drive Style (e.g., rear, mid, front)	Front-wheel drive	Rear-wheel drive	Different
Motor Type	24 DC brush differential front axle	24V DC brush differential rear axle	S.E.
Motor Output	24V 180W	24V 180W	S.E.
Batteries	Lithium battery	Lithium battery	S.E.
Range per Charge	6 hours	6 hours	S.E.
Charger Type (On-board/Off-board/Carry- on)	Carry-on	Carry-on	S.E.
Charger Input / Output Power	100-240VAC 50/60Hz 2A	100-240VAC 50/60Hz 1.2.-0.5A	Similar
Actuator	Intelligent, Regenerative and Electromagnetic brake system	Intelligent, Regenerative and Electromagnetic brake system	S.E.

Brake	Electromagnetic brake	Electromagnetic brake	S.E.
Minimum braking distance and time	0.7 meter for the speed of 6km/h <1s	1.1 meter for the speed of 6km/h <1s	S.E.(Note 1)
Wheel Lock (type)	electromagnetic brake	electromagnetic brake	S.E.
Max speed Forward	6 km/h	6 km/h	S.E.
Max speed Reverse	2 km/h	3 km/h	S.E.(Note 1)
Rear Wheels Size	10 inches	8 inches	Similar
Front Tire Size	8 inches	7 inches	Similar
Tire Pressure (if pneumatic)	N/A	NA	S.E.
Anti-tip Wheels	N/A	2.5 inches	Different.
Maximum Occupant Mass	120 KG	120 KG	S.E
Curb Climbing ability	40 mm	60 mm	Different
Ground clearance	100 mm	50 mm	Different
Minimum Turning Radius	1.97 m	1.2m	Different
Maximum Incline	≥ 15° for all directions	≥ 15° for all directions	S.E.
Footplates	Aluminum	ABS plastics	Different
Back Upholstery	Leather package	Leather package	S.E
Operating surface & environment	Indoor and outdoor use	Indoor and outdoor use	S.E.

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.
EMC	ISO7176-21: Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically

	powered wheelchairs and scooters, and battery chargers
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 7176-14: Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods ISO 7176-16: Wheelchairs - Part 16: Resistance to ignition of postural support devices

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 the legally marketed device.