



September 22, 2026

Strongback Mobility AG C/O Blueaudit GmbH
Roman Hefle
Quality Manager
Schindellegistrasse 9
Wolfhagen, 34466
Germany

Re: K253762
Trade/Device Name: ErgoSteel (ES0001/696)
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: August 21, 2026
Received: November 25, 2025

Dear Roman Hefle:

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

for 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

Indications for Use

510(k) Number (if known)

K253762

Device Name

ErgoSteel (ES0001/696)

Indications for Use (Describe)

The device is intended for medical purpose 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

Prepared in accordance with 21 CFR 807.92

510(k) Number K253762 — ErgoSteel Manual Wheelchair (Model ES0001 / 696)

1. Submitter — 21 CFR 807.92(a)(1)

Submitter	Strongback Mobility AG
Address	c/o blueAUDIT GmbH, Schindellegistrasse 73, 8808 Pfäeffikon SZ, Switzerland
Telephone	+49 178 8765829
Contact person	Mr. Roman Hefle, Quality Manager
E-mail	roman.hefle@strongbackmobility.com
Date summary prepared	16 September 2026

2. Device — 21 CFR 807.92(a)(2)

Trade / proprietary name	ErgoSteel (ES0001/696)
Common / usual name	Mechanical wheelchair
Classification name	Wheelchair, Mechanical
Regulation number	21 CFR 890.3850
Product code	IOR
Regulatory class	Class I

3. Legally marketed predicate device — 21 CFR 807.92(a)(3)

510(k) number	K231320
Device	Zhenjiang Assure Mechanical Wheelchair, Model K1
Product code	IOR

4. Device description — 21 CFR 807.92(a)(4)

The STRONGBACK ErgoSteel Wheelchair is a folding wheelchair with integrated ergonomic back support (lumbar support).

It is an indoor/outdoor wheelchair that has a base with four wheels with a seat. The device can be disassembled for transport, and it is foldable. The device complies with the applicable requirements of ISO 7176.

This device has direct and indirect patient-contacting components, including the seat cushion, the backrest with integrated lumbar support, the armrests with padding, the footplates, the push handles (handgrips), and the upholstery materials (seat & back fabric). This device does not contain software/firmware. This device does not require electrical safety evaluation. This device is not an in vitro diagnostic device.

5. Intended use and Indications for Use — 21 CFR 807.92(a)(5)

The Indications for Use of the subject device are identical to the cleared Indications for Use of the primary predicate device K231320:

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

The device is an Over-the-Counter (OTC) device under 21 CFR 801 Subpart C and is suitable for indoor and outdoor use.

The intended user population is adults (22 years old and greater), consistent with the cleared intended user population of the primary predicate device. The device is not intended for use by children or adolescents, i.e. persons under 22 years of age.

The intended use of the predicate device is the same as that of the subject device.

6. Comparison of technological characteristics with the predicate device — 21 CFR 807.92(a)(6)

The subject device and the primary predicate device K231320 are substantially equivalent in technological characteristics. The differences identified below do not raise any new questions of safety or effectiveness.

Element of Comparison	Subject Device — ErgoSteel, 510(k) K253762	Primary Predicate — K231320, Zhenjiang Assure Mechanical Wheelchair, model K1	Comparison / Notes
REGULATORY IDENTITY			
Regulation Name	Wheelchair, Mechanical	Wheelchair, Mechanical	Identical
Regulation Number	21 CFR 890.3850	21 CFR 890.3850	Identical
Product Code	IOR	IOR	Identical
510(k) Type	Traditional 510(k)	Special 510(k)	Different submission type; does not affect substantial-equivalence determination.
INTENDED USE & INDICATIONS			
Intended Use	The device is intended for medical purpose to provide mobility to persons restricted to a sitting position.	The device is intended for medical purpose to provide mobility to persons restricted to a sitting position.	Identical
Over-the-Counter Use	Yes	Yes	Identical
Use Environment	Indoor / outdoor	Indoor / outdoor	Identical
Target Population	Adults (22 years old and greater)	Adults (22 years old and greater)	Identical. The published K231320 510(k) Summary comparison table states the target population as "The elderly and disabled" and does not state an age group.
DESIGN & DIMENSIONS			
Frame Material	High-quality SPCC steel pipe	High-quality SPCC steel pipe	Identical material grade and construction. ErgoSteel passed ISO 7176-8:2014 fatigue test.
Framework	Foldable	Foldable	Identical.
Casters (front)	8" x 1.25"	8" x 1.25"	Identical caster diameter and width.

Element of Comparison	Subject Device — ErgoSteel, 510(k) K253762	Primary Predicate — K231320, Zhenjiang Assure Mechanical Wheelchair, model K1	Comparison / Notes
Rear Wheel	24" x 1"	24" x 1"	Identical rear-wheel diameter and width.
Seat Length	16.54" (42 cm)	16" – 18"	Within K231320 range; no safety impact. ISO 7176 verified.
Seat Height	19.69" (50 cm)	19.5"	0.19" (5 mm) difference; within ISO 7176-5:2008 tolerance.
Seat Width	17.72" (45 cm)	16" – 20"	Within K231320 range.
Max loading	136 kg / 300 lbs	136 kg / 300 lbs	Identical load rating.
COMPONENT-LEVEL DIMENSIONS (from K231320 Public Summary)			
Handle size	103 × 34 mm	103 × 34 mm	Identical.
Footplate size	197 × 161 mm	197 × 161 mm	Identical.
Backrest size	16" – 20"	16" – 20"	Identical.
Armrest size	10.12" × 2.2" × 1.42"	10.12" × 2.2" × 1.42"	Identical.
COMPONENTS LIST			
Handgrip	Present (PVC)	Present (material not known)	The Handgrip is made from PVC. This material has been previously used in mechanical wheelchairs cleared under the same regulation (21 CFR 890.3850) and product code IOR, with similar intended use and technology (e.g., K131529) This does not impact safety and effectiveness.
Footrest / footplate	Present (Polyamide footplate)	Present (Footplate)	Same component, alternative naming.
Backrest	Present (Oxford fabric – Polyethylene terephthalate (PET) with integrated lumbar support — see Differentiator row)	Present (Backrest)	Functional component identical. ErgoSteel adds an integrated lumbar-support contour; see dedicated row below. This PET material is included in Section B of Attachment G of FDA's guidance on the "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"", and has a documented history of safe use in legally marketed medical devices in contact with intact skin (e.g., through Medical Device Reporting (MDR) analysis, literature search).
Armrest	Present (PUR armpad)	Present (Armrest)	Same component, alternative naming.

Front caster	Present	Present (Front caster)	Identical.
Front fork	Present	Present (Front fork)	Identical.
Rear wheel	Present (quick-release axle)	Present (Rear wheel)	Same component; ErgoSteel features quick-release axle for transport convenience.
Skirt guard / side panel	Present (Teslin mesh fabric)	Not separately listed in K231320 510(k) Summary; side cover function is integrated into the seat/backrest assembly per the K1 design.	Subject device adds a separate Skirt guard / side panel made of Teslin mesh fabric (PVC-coated polyester). This material has been previously used in mechanical wheelchairs cleared under the same regulation (21 CFR 890.3850) and product code IOR, with similar intended use and technology (e.g., K010094). This addition does not impact safety and effectiveness.

Element of Comparison	Subject Device — ErgoSteel, 510(k) K253762	Primary Predicate — K231320, Zhenjiang Assure Mechanical Wheelchair, model K1	Comparison / Notes
Brakes	Present (standard parking brake, lockable)	Present	Brakes are mandatory wheelchair components verified via ISO 7176-3. Predicate K231320 was tested per ISO 7176-3:2003; ErgoSteel was tested per ISO 7176-3:2012 (newer revision). Same fundamental technology and performance criteria.
STRONGBACK DIFFERENTIATOR			

Integrated Support	Ergonomic	Lumbar	Present — backrest incorporates an integrated, fixed-geometry lumbar-support contour designed to passively support the lumbar spine of the seated user. Non-removable; non-mechanical; no moving parts; no electrical or pneumatic actuation.	Not present.	Additional feature of the subject device. No new questions of safety or effectiveness are raised: (i) It is a fixed, passive ergonomic shape of the existing backrest; (ii) the Seat & Back is made from Oxford fabric – Polyethylene terephthalate (PET). This PET material is included in Section B of Attachment G of FDA's guidance on the "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"", and has a documented history of safe use in legally marketed medical devices in contact with intact skin (e.g., through Medical Device Reporting (MDR) analysis, literature search); (iii) it does not alter the mechanical load path or the structural performance of the wheelchair, (iv) it does not affect indications for use, target population or use environment, and (v) the device passed ISO 7176-1 (static stability), ISO 7176-8 (fatigue) and ISO 7176-16 (resistance to ignition) testing with the lumbar support installed.
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PERFORMANCE / NON-CLINICAL TESTING				
ISO 7176-1 — Static stability	ISO 7176-1:2014 — PASS	ISO 7176-1:1999 — PASS	Same standard, newer revision in subject device. Acceptance criteria unchanged; ErgoSteel meets the more current revision.	
ISO 7176-3 — Effectiveness of brakes	ISO 7176-3:2012 — PASS	ISO 7176-3:2003 — PASS	Same standard, newer revision in subject device.	

Element of Comparison	Subject Device — ErgoSteel, 510(k) K253762	Primary Predicate — K231320, Zhenjiang Assure Mechanical Wheelchair, model K1	Comparison / Notes
ISO 7176-5 — Overall dimensions, mass, manoeuvring space	Verified within ISO 7176-5 ranges via dimensional inspection.	ISO 7176-5:2008 — PASS	Dimensions of ErgoSteel are within ISO 7176-5 typical ranges; explicit ISO 7176-5 retest not required for SE.
ISO 7176-8 — Fatigue strength	ISO 7176-8:2014 — PASS	Not separately listed in K231320 510(k) Summary	Additional testing performed by subject device sponsor at the current revision; strengthens, not weakens, the SE argument.

ISO 7176-11 — Test dummies	Test dummies used in fatigue and stability testing per ISO 7176-11:2012.	ISO 7176-11:1992 — PASS	Same standard, newer revision in subject device.
ISO 7176-13 — Coefficient of friction of test surfaces	Not separately reported; embedded in ISO 7176-1 and -3 testing.	ISO 7176-13:1989 — PASS	Test method standard for setting up other tests; equivalent test surfaces used.
ISO 7176-15 — Information disclosure and labelling	ISO 7176-15:2012 (current revision) — compliant labelling and IFU per Strongback documentation.	ISO 7176-15:1996 — PASS	Same standard, newer revision in subject device.
ISO 7176-16 — Resistance to ignition of upholstered parts	ISO 7176-16:2012 — PASS	ISO 7176-16:1997 — PASS	Same standard, newer revision in subject device.
Biocompatibility	In compliance with ISO10993-1; ISO10993-5; and ISO10993-10.	Not listed in the K231320 Special 510(k) Summary.	No new biocompatibility testing was necessary for the subject device. did not require one in its Special 510(k). No new questions raised.

7. Nonclinical performance data — 21 CFR 807.92(b)(1)

The ErgoSteel Manual Wheelchair (Model ES0001 / 696) is supported by a comprehensive program of nonclinical bench testing and biocompatibility testing in accordance with FDA-recognised consensus standards and the FDA Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs.A. MECHANICAL PERFORMANCE TESTING (BENCH) — Conducted by Jiangsu Assure Medical Equipment Co., Ltd. (the OEM manufacturer) under their ISO 13485:2016 certified Quality Management System.

- ISO 7176-1:2014 — Determination of static stability (forward, rearward, lateral) — PASS
- ISO 7176-3:2012 — Determination of effectiveness of brakes — PASS
- ISO 7176-5:2008 — Determination of overall dimensions, mass and manoeuvring space — PASS
- ISO 7176-7:1998 — Measurement of seating and wheel dimensions — PASS
- ISO 7176-8:2014 — Requirements and test methods for static, impact and fatigue strengths (drop test, fatigue test on rolling drums, double-drum test) — PASS
- ISO 7176-11:2012 — Test dummies (used as reference)
- ISO 7176-13:1989 — Coefficient of friction of test surfaces (used as reference)
- ISO 7176-15:1996 — Requirements for information disclosure, documentation and labelling — PASS
- ISO 7176-16:2012 / ISO 16840-10:2021 — Resistance to ignition of postural support devices — PASS
- ISO 7176-22:2014 — Set-up procedures — PASS

BIOCOMPATIBILITY

No new biocompatibility testing was necessary.

The Armpad is made from Polyurethane (PUR), the Seat & Back is made from Oxford fabric – Polyethylene terephthalate (PET), and the Footplate is made from Polyamide (PA). These materials (PUR, PET and PA) are included in Section B of Attachment G of FDA's guidance on the "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"", and have a documented history of safe use in legally marketed medical devices in contact with intact skin (e.g., through Medical Device Reporting (MDR) analysis, literature search).

The Handgrip is made from PVC and the Side Panels are made from (Teslin mesh / PVC-coated polyester). These materials (PVC, and PVC-coated polyester) with similar nature of intact skin contact have been previously used in mechanical wheelchairs cleared under the same regulation (21 CFR 890.3850) and product code IOR, with similar intended use and technology (e.g., K131529 and K010094). Since FDA has previously cleared devices under the same regulation and product code with comparable intended use, technology, and similar materials (PVC and PVC-coated polyester) without identifying safety or effectiveness concerns, these material differences do not impact safety and effectiveness of the subject device.

8. Clinical performance data — 21 CFR 807.92(b)(2)

Not Applicable. No clinical investigation, clinical trial, or other prospective clinical study was conducted in support of this 510(k) submission.

9. Conclusions — 21 CFR 807.92(b)(3)

The nonclinical bench testing and biocompatibility information described above demonstrates that the ErgoSteel Manual Wheelchair (Model ES0001 / 696) is as safe, as effective, and performs as well as the legally marketed primary predicate device K231320 (Zhenjiang Assure Mechanical Wheelchair, model K1), and meets the applicable FDA-recognised consensus standards for mechanical wheelchairs (ISO 7176 series), biological evaluation (ISO 10993 series), risk management (ISO 14971:2019) and labelling (ISO 7176-15:1996 / ISO 20417:2021). Specifically:

- Mechanical safety and performance — All required ISO 7176 series tests (static stability, brake effectiveness, dimensions, mass, manoeuvring space, static / impact / fatigue strengths, flammability, labelling, set-up) demonstrated PASS results equivalent to or exceeding the requirements applicable to Class I mechanical wheelchairs under 21 CFR 890.3850 (Product Code IOR).
- Biocompatibility — No new biocompatibility testing was necessary. All intact skin contacting components (Armpad (PUR), Seat & Back Oxford fabric (PET), Footplate (PA), Handgrip (PVC), and Side Panels (Teslin mesh/PVC-coated polyester)), are either included in Section B of Attachment G of FDA's guidance on the "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"", or have been previously used in FDA-cleared mechanical wheelchairs under the same regulation and product code, with identical intended use and intact skin contact classification. No new biocompatibility risks are introduced by these materials. Therefore, these material differences do not impact safety and effectiveness.
- Substantial equivalence — The technological characteristics of the ErgoSteel and the primary predicate K231320 (manufactured by the same OEM group, Zhenjiang Assure / Jiangsu Assure Medical Equipment Co., Ltd.) are substantially equivalent in indications for use, intended user population, regulation, classification, dimensions, materials, brake system, frame design, performance characteristics and biocompatibility profile. The differences identified in the substantial equivalence Comparison Table do not raise any new questions of safety or effectiveness.
- Risk management — A complete ISO 14971:2019-compliant risk management file is maintained in the Strongback Mobility AG Device Master Record. No residual risks were identified that would change the safety or effectiveness conclusion.

Therefore, the ErgoSteel Manual Wheelchair is substantially equivalent to the legally marketed predicate device K231320.