October 24, 2025

Wandercraft SAS
Mélanie Combes
Head of Regulatory and Quality Affairs
88 Rue de Rivoli
Paris, Ile-de-France, 75004
France

Re: K250904
Trade/Device Name: Atalante X
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered lower extremity exoskeleton
Regulatory Class: Class II
Product Code: PHL
Dated: September 22, 2025
Received: September 22, 2025

Dear Mélanie Combes:

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,

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.	K250904

Please provide the device trade name(s).

Atalante X

Please provide your Indications for Use below.

Atalante X is intended to perform ambulatory functions and mobility exercises, hands-free, in rehabilitation institutions under the supervision of a trained operator for the following populations:
* Individuals with hemiplegia due to cerebrovascular accident (CVA)
* Individuals with spinal cord injuries at levels C4 to L5 (SCI)
* Individuals with multiple sclerosis (MS)

The operator must complete a training program prior to use of the device.

Atalante X is intended to be used on adolescents of 18 years and older, and adults able to tolerate a stand-up position.

The device is not intended for sports or stair climbing.

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
K250904

1. Submission Sponsor

Wandercraft SAS
88 rue de Rivoli
75004 Paris, France

Contact: Matthieu Masselin
Title: Chief Executive Officer

2. Submission Correspondent

Wandercraft SAS
88 rue de Rivoli
75004 Paris, France
Email: reglementaire@wandercraft.health

Contact: Mélanie Combes
Title: Head of Regulatory and Quality Affairs

3. Date Prepared

March 25th, 2025

4. Device Identification

Trade/Proprietary Name:	Atalante X
Common/Usual Name:	Powered Exoskeleton
Classification Name:	Powered lower extremity exoskeleton
Regulation Number:	890.3480
Product Code:	PHL
Class:	II
Classification Panel:	Neurological and Physical Medicine Devices (OHT5)

5. Legally Marketed Predicate and Reference Devices

	Predicate Device	Reference Device
Device name	Atalante X	EksoNR
510(K) number	K232077	K220988
Regulation Number	21 CFR 890.3480	21 CFR 890.3480
Regulation Name	Powered Exoskeleton	Powered Exoskeleton
Product code	PHL	PHL
Review Panel	Neurology	Neurology
Manufacturer	Wandercraft SAS	Ekso Bionics Inc.

6. Indication for Use Statement

Atalante X is intended to perform ambulatory functions and mobility exercises, hands-free, in rehabilitation institutions under the supervision of a trained operator for the following populations:

- Individuals with hemiplegia due to cerebrovascular accident (CVA)
- Individuals with spinal cord injuries at levels C4 to L5 (SCI)
- Individuals with multiple sclerosis (MS)

The operator must complete a training program prior to use of the device.

Atalante X is intended to be used on adolescents of 18 years and older and adults, able to tolerate a stand-up position.

The device is not intended for sports or stair climbing.

7. Device Description

Atalante X is a completely self-balancing walking system for people with mobility disabilities. It is a fully powered hip-knee-ankle lower body exoskeleton with 12 actuated degrees of freedom. Atalante X is self-balancing and includes dynamic-walking control. Dynamic-walking allows the Atalante X to consume significantly less power and have a more natural gait.

8. Substantial Equivalence Discussion

The following table compares Atalante X to the predicate and reference devices with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate.

Table 1 – Comparison of Characteristics

FEATURE	Subject Device Atalante X	Predicate Device Atalante X	Reference Device EksoNR
510(k) Number	K250904	K232077	K220988
Manufacturer	Wandercraft SAS	Wandercraft SAS	Ekso Bionics Inc.
Product Code	PHL	PHL	PHL
Regulation	890.3480	890.3480	890.3480
Regulation Name	Powered Exoskeleton	Powered Exoskeleton	Powered Exoskeleton
Indications for Use	Atalante X is intended to perform ambulatory functions and mobility exercises, hands-free, in rehabilitation institutions under the supervision of a trained operator for the following populations: - Individuals with hemiplegia due to cerebrovascular accident (CVA). - Individuals with spinal cord injuries at levels C4 to L5 (SCI). - Individuals with multiple sclerosis (MS). The operator must complete a training program prior to use of the device. Atalante X is intended to be used on adolescents of 18 years and older, and adults able to tolerate a stand-up position. The device is not intended for sports or stair climbing.	Atalante X is intended to perform ambulatory functions and mobility exercises, hands-free, in rehabilitation institutions under the supervision of a trained operator for the following populations: - Individuals with hemiplegia due to cerebrovascular accident (CVA). - Individuals with spinal cord injuries at levels T5 to L5 (SCI). The operator must complete a training program prior to use of the device. Atalante X is intended to be used on adolescents of 18 years and older, and adults able to tolerate a stand-up position. The device is not intended for sports or stair climbing.	The EksoNR is intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for the following populations: - Individuals with multiple sclerosis (upper extremity motor function of at least 4/5 in at least one arm). - Individuals with acquired brain injury, including traumatic brain injury and stroke (upper extremity motor function of at least 4/5 in at least one arm). - Individuals with spinal cord injuries at levels T4 to L5 (upper extremity motor function of at least 4/5 in both arms). - Individuals with spinal cord injuries at levels of C7 to T3 (ASIA D with upper extremity motor function of at least 4/5 in both arms). The therapist must complete a training program prior to use of the device. The devices are not intended for sports or stair climbing.
Population	Adolescents of 18 years and older, and adults	Adolescents of 18 years and older, and adults	Adolescents of 18 years and older, and adults
Environment	Rehabilitation institutions	Rehabilitation Institutions	Rehabilitation Institutions

FEATURE	Subject Device Atalante X	Predicate Device Atalante X	Reference Device EksoNR
Body Coverage	Worn over legs and upper body with rigid torso	Worn over legs and upper body with rigid torso	Worn over legs and upper body with rigid torso
Size of Components	Adjustable upper leg, lower leg. Non-adjustable hip width	Adjustable upper leg, lower leg. Non-adjustable hip width	Adjustable upper leg, lower leg, and hip width
Control Unit	Control unit integrated into the torso	Control unit integrated into the torso	Control unit integrated into the torso
Mobility Aid	None	None	Walker, Crutches, Cane
User Mobility	Sit, stand, walk, turn, exercise (weight shift, squat), repositioning	Sit, stand, walk, turn, exercise (weight shift, squat), repositioning	Sit, stand, walk, and turn
Walking Speed	~2km/hr	~2km/hr	~2 km/hr
Type of Surface	Smooth	Smooth	Smooth, cement, carpet
Range of Motion	Hip: 90° flexion, 5° extension; 17° abduction, 10° adduction; 10° medial rotation, 20° lateral rotation Knee: 110° Flexion; -5°Extension Ankle: 0° dorsiflexion, 9° plantar flexion	Hip: 90° flexion, 5° extension; 17° abduction, 10° adduction; 10° medial rotation, 20° lateral rotation Knee: 110° Flexion; -5°Extension Ankle: 0° dorsiflexion, 9° plantar flexion, 18° pronation and supination	Hip: 135° flexion to 20° extension Knee: 130° flexion to 0° extension Ankles: 10° flexion to 10° extension
Rechargeable Battery	Rechargeable Lithium-ion battery 46.8 V, 6,4Ah Usage duration: 2h of continuous usage per charge	Rechargeable Lithium-ion battery 46.8 V, 6,4 Ah Usage duration: 2h of continuous usage per charge	Rechargeable Lithium-ion battery. 48.1V, 30A peak current Usage duration: 1h of continuous usage per charge
Battery Charge Time	2h 30min	2h30min	1h
Training Program	Yes	Yes	Yes
Certification Program	Yes	Yes	Yes
User Feedback	Provides visual feedback on the handheld controller and physio interface, and auditory feedback	Provides visual feedback on the handheld controller and physio interface, and auditory feedback	Provides visual feedback on the handheld controller and auditory feedback
Fall Detection and Mitigation	Must be used in combination with safety system	Must be used in combination with safety rail	None
Failsafe Feature	(use of safety system)	(use of safety rail)	In the event of power failure knees become locked and hips free (similar to typical passive leg braces)

FEATURE	Subject Device Atalante X	Predicate Device Atalante X	Reference Device EksoNR
Electrical Testing	IEC 60601-1	ANSI AAMI ES60601-1	IEC 60601-1
EMC Testing	IEC 60601-1-2 AIM 7351731	IEC 60601- 1-2 AIM 7351731	IEC 60601-1-2

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of Atalante X and to show substantial equivalence to the predicate and reference devices, Wandercraft SAS completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. Atalante X passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate:

- Cytotoxicity testing per ISO 10993-5: Passed
- Irritation and Sensitization testing per ISO 10993-10: Passed
- Electrical safety testing per IEC 60601-1: Passed
- Electromagnetic Interference (EMI) testing per IEC 60601-1-2: Passed
- Software verification and validation per IEC 62304 and FDA Guidance – the current version has been fully validated
- System (Device) Verification and Validation: Passed
- Electronics Sub-system Verification: Passed
- Mechanics Sub-system Verification: Passed
- Cycling Testing: Passed
- Thermal Testing: Passed
- Useful Life Testing – supports 5 years
- Transportation Testing per ASTM D4169 – demonstrates package integrity is maintained: Passed

10. Clinical Performance Data

The current device was evaluated in four previous prospective studies to demonstrate its safety and effectiveness for the indicated use (K232077). This submission builds upon those studies with additional clinical trials to support its safety and effectiveness for an expanded indication.

A retrospective study included 33 patients with spinal cord injuries (SCI) at levels C4 to T4 who used the Atalante X device as part of their rehabilitation program. Additionally, a prospective study involving 14 patients with multiple sclerosis (MS) was conducted. The device was shown to facilitate ambulatory function at speeds comparable to the predicate device, while allowing the upper limbs to remain free for other tasks. Furthermore, an interim report from a second prospective clinical trial involving four patients with MS provided supplementary safety and performance data.

Across these studies, non-serious adverse events included fatigue/dizziness, muscle pain, shoulder pain and minor skin issues. No serious adverse events were observed.

These findings are further supported by real-world data from over 978 patients who completed at least three sessions with Atalante X, including 212 CVA patients, 136 SCI patients (7 at levels C2-C3, 59 at levels C4-T4, 67 at levels T5-L5 and 3 with unknown lesion levels) and 99 MS patients.

In conclusion, the clinical data demonstrate that the Atalante X can be used safely and effectively by patients with SCI at levels C4-T4 and by those with MS.

11. Training

Prior to the first use of Atalante X, to ensure safe and effective operation of the device, the operator must complete a certification training. To optimize the integration of the technology in the clinical setting, such training is then followed by frequent visits by Wandercraft Customer Care to further support the operator with the exoskeleton. The training program is offered for as many operators as agreed in the contract signed with the customer.

Training is composed by a theoretical part including presentation and description of the whole system and its mode of operations and a hands-on practice. This latter will be performed both in pairs – with an operator in the role of "operator" and another operator in the role of a "patient" – and in individual sessions. The double role allows the operators to understand the device from both the operator's and patient's perspectives.

An operator is considered certified, i.e., with proven competence to safely operate Atalante X alone with the patient, only after fulfilling all eligibility requirements and pass the certification evaluation.

12. Statement of Substantial Equivalence

Atalante X has the same intended use as the predicate and reference devices, Atalante X (K232077) and EksoNR (K220988), and the same or similar technological characteristics. Compared to the predicate device Atalante X (K232077), the new version differs in its indications for use. The new version includes expanded indications for individuals with high spinal cord injuries from C4 to L5 and for individuals with multiple sclerosis, as supported by clinical studies. These differences in indications and technological characteristics do not raise new or different questions of safety or effectiveness. Performance testing has demonstrated that the updated Atalante X is as safe and effective as the predicate device. Therefore, Atalante X is substantially equivalent to the predicate device.