December 13, 2023

Wandercraft SAS
Maria Iacono, PhD
Director of Regulatory and Quality Affairs
88 rue de Rivoli
Paris, Ile-de-France 75004
France

Re: K232077
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: November 24, 2023
Received: November 24, 2023

Dear Dr. Iacono:

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.

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 Rehabilitation 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.

510(k) Number *(if known)*
K232077

Device Name
Atalante X

Indications for Use *(Describe)*
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.

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) Summary
Atalante X

1. Submission Sponsor

Wandercraft SAS
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Contact: Matthieu Masselin
Title: Chief Executive Officer

2. Submission Correspondent

Wandercraft SAS
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Contact: Maria Ida Iacono, PhD
Title: Chief of Regulatory, Quality, and Clinical Affairs – Global

3. Date Prepared

July 13th, 2023

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 Devices

	Primary Predicate	Secondary Predicate
Device name	Atalante	Indego®
510(K) number	K221859	K173530
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	Parker Hannifin Corp.

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 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.

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 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 devices.

Table 5A – Comparison of Characteristics

FEATURE	Subject Device Atalante X	Primary Predicate Atalante	Secondary Predicate Indego®
510(k) Number	TBD	K221859	K173530
Manufacturer	Wandercraft SAS	Wandercraft SAS	Parker Hannifin Corp.
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 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 Atalante exoskeleton is intended to enable individuals with **hemiplegia due to cerebrovascular accident (CVA)** to perform ambulatory functions and mobility exercises, hands-free, in rehabilitation institutions under the supervision of a trained operator. The operator must complete a training program prior to use of the device. The Atalante system 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 Indego® orthotically fits to the lower limbs and the trunk; the device is intended to enable individuals with spinal cord injury at levels T3 to L5 to perform ambulatory functions with supervision of a specially trained companion in accordance with the user assessment and training certification program. The device is also intended to enable individuals with **SCI at levels C7 to L5** to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. Finally, the Indego® is also intended to enable individuals with **hemiplegia** (with motor function of 4/5 in least one upper extremity) **due to cerebrovascular accident (CVA)** to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. The Indego is not intended for sports or stair climbing.
Population	Adolescents of 18 years and older, and adults	Adolescents of 18 years and older, and adults	Adults over age of 18
Environment	Rehabilitation institutions	Rehabilitation Institutions	Rehabilitation Institutions
Body Coverage	Worn over legs and upper body with rigid torso	Worn over legs and upper body with rigid torso	Worn over legs and around hips with lower torso
Size of Components	Adjustable upper leg, lower leg. Non-adjustable hip width;	Adjustable upper leg, lower leg. Non-adjustable hip width;	Modular Small, Medium and Large upper leg, lower leg and hip components;
Mobility Aid	None	None	Walker, Crutches, Cane

FEATURE	Subject Device Atalante X	Primary Predicate Atalante	Secondary Predicate Indego®
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 Knees: 110° Flexion; -5°Extension: Ankle: 0 dorsiflexion, 9° plantar flexion, 18° pronation and supination	Hip: 90° flexion, 5° extension; 17° abduction, 10° adduction; 10° medial rotation, 20° lateral rotation Knees: 110° Flexion; -5°Extension: Ankle: 0 dorsiflexion, 9° plantar flexion, 18° pronation and supination	Hips: 110° flexion to 30° extension Knees: 110° 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, 9 Ah Usage duration: 2h of continuous usage per charge	Rechargeable lithium ion. 33.3 V, 36A peak current, 12A continuous current. 159Wh fully charged; Usage duration: 1.5h of continuous usage per charge
Battery Charge Time	2h 30min	4h	4h
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 operator interface, and auditory feedback	Provides vibratory feedback and LED indicators on top of hip unit, visible to wearer
Fall Detection and Mitigation	Must be used in combination with safety rail	Must be used in combination with safety rail	Detects forward, backward and sideways falling as it is happening; the device makes adjustments during the course of the fall to position the user for minimal risk of injury or allow the user to attempt to recover unassisted
Failsafe Feature	(use of safety rail)	(use of safety rail)	In the event of power failure knees become locked and hips free (similar to typical passive leg braces)
Electrical Testing	ANSI AAMI ES60601-1:2005/(R)2012 AndA1:2012.	ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012	ANSI/AAMI ES60601-1:2005/(R)2012
EMC Testing	IEC 60601-1-2 2020 AIM 7351731:2021	IEC 60601- 1-2:2014 AIM 7351731:2021	IEC 60601-1-2: 2014

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of Atalante X and to show substantial equivalence to the predicate 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 devices:

- Cytotoxicity testing per ISO 10993-5: Passed
- Irritation and Sensitization testing per ISO 10993-10: Passed
- Electrical safety testing per ANSI/AAMI 60601-1: Passed
- Electromagnetic Interreference (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

Two clinical studies with a total of 21 patients with spinal cord injury (SCI) were undertaken. The device could ensure ambulatory functions with comparable speed to that of the predicates while leaving upper limbs free potentially for additional tasks. The findings are supported by real world evidence of use by over 481 patients which performed 3 sessions or more, including 40 SCI patients at levels C3-L3 who performed a total of 560 sessions.

There were altogether 24 adverse events in both clinical studies, majority of which were minor skin lesions, one occurrence of nausea and one of incontinence. None of them was serious.

Clinical data demonstrate that patients with SCI at levels T5-L5 can use Atalante X safely and effectively.

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 Atalante and Indego® predicate devices, and the same or similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Performance testing has demonstrated that Atalante X is as safe and effective as the predicate devices. Therefore, Atalante X is substantially equivalent to the predicate devices.