December 29, 2022

Wandercraft SAS
% Andre Kindsvater
Senior Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road Building 1
Suite 300
Austin, Texas 78746

Re: K221859
Trade/Device Name: Atalante
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered Lower Extremity Exoskeleton
Regulatory Class: Class II
Product Code: PHL
Dated: June 22, 2022
Received: June 27, 2022

Dear Andre Kindsvater:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221859

Device Name
Atalante

Indications for Use *(Describe)*
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.

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

Atalante

1. **Submission Sponsor**

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Contact: Matthieu Masselin
Title: Chief Executive Officer

2. **Submission Correspondent**

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Contact: André Kindsvater
Title: Senior Consultant RA & QA

3. **Date Prepared**

June 22nd, 2022

4. **Device Identification**

Trade/Proprietary Name:	Atalante
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	Reference Device
Device name	Indego®	Ekso™ (v.1.1) and Ekso GT™ (v.1.2)
510(K) number	K173530	K143690

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	Parker Hannifin Corp	Ekso Bionics Inc.

6. Indication for Use Statement

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.

7. Device Description

The Atalante 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 is self-balancing and includes dynamic-walking control. Dynamic-walking allows the Atalante to consume significantly less power and have a more natural gait.

8. Substantial Equivalence Discussion

The following table compares the Atalante 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 device.

Table 5A – Comparison of Characteristics preliminary

	Subject Device	**Predicate**	**Reference Device**
FEATURE	**Atalante**	**Indego®**	**Ekso Ekso™ (v.1.1) and Ekso GT™ (v.1.2)**
510(k) Number	K221859	K173530	K143690
Manufacturer	Wandercraft SAS	Parker Hannifin Corp.	Ekso Bionics Inc.
Product Code	PHL	PHL	PHL
Regulation	890.3480	890.3480	890.3480
Regulation Name	Powered Exoskeleton	Powered Exoskeleton	Powered Exoskeleton

	Subject Device	Predicate	Reference Device
FEATURE	**Atalante**	**Indego®**	**Ekso Ekso™ (v.1.1) and Ekso GT™ (v.1.2)**
Indications for Use	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 spinal cord injury 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.	The Ekso™ (version 1.1) and Ekso GT™ (version 1.2) are intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for the following population with upper extremity motor function of at least 4/5 in both arms: Individuals with hemiplegia due to stroke, Individuals with spinal cord injuries at levels T4 to L5, and Individuals with spinal cord injuries at levels of C7 to T3 (ASIA D). The therapist must complete a training program prior to use of the device. The devices are not intended for sports or stair climbing.

	Subject Device	Predicate	Reference Device
FEATURE	**Atalante**	**Indego®**	**Ekso Ekso™ (v.1.1) and Ekso GT™ (v.1.2)**
Population	Adolescents of 18 years and older, and adults	Adults over age of 18	Adults over age of 18
Environment	Rehabilitation centers	CVA population cleared only for use in Rehabilitation centers	Rehabilitation centers
Body Coverage	Worn over legs and upper body with rigid torso	Worn over legs and around hips with lower torso	Worn over legs and upper body with rigid torso
Size of Components	Adjustable upper leg, lower leg. Non adjustable hip width;	Modular Small, Medium and Large upper leg, lower leg and hip components;	Adjustable upper leg, lower leg, and hip width;
Mobility Aid	None	Walker, Crutches, Cane	Walker, Crutches, Cane
User Mobility	Sit, stand, walk, turn, exercise (weight shift, squat), repositioning	Sit, stand, walk, and turn	Sit, stand, walk, exercises (weight shift) and turn
Walking Speed	~2km/hr	~2 km/hr	~2 km/hr
Type of Surface	Smooth	Smooth, cement, carpet	Smooth, cement,carpet
Range of Motion	Hip: 90° flexion, 5° extension; 17° abduction, 10° adduction; 10° medial rotation, 20° lateral rotation Knee: 110° flexion to -5° extension (flexum). Ankle: 0 dorsiflexion, 9° plantar flexion, 18° pronation and supination	Hips: 110° flexion to 30° extension Knees: 110° flexion to 10° extension	Hips: 135° flexion to 20° extension Ankles: 0° dorsiflexion to 25° plantar extension
Rechargeable Battery	Rechargeable lithium-ion battery 46.8 V, 9 Ah Usage duration: 2 hours of continuous usage per charge	Rechargeable lithium ion. 33.3 V, 36A peak current, 12A continuous current. 159Wh fully charged; Usage duration: 1.5 hours of continuous usage per charge	Rechargeable lithium ion batteries 48.1V, 30A peak current, 1 hour of continuous usage per charge
Battery Charge Time	4 hours	4 hours	1 hour
Training Program	Yes	Yes	Yes

	Subject Device	Predicate	Reference Device
FEATURE	**Atalante**	**Indego®**	**Ekso Ekso™ (v.1.1) and Ekso GT™ (v.1.2)**
Certification Program	Yes	Yes	Yes
User Feedback	Provides visual feedback on the handheld controller and physio interface, and auditory feedback.	Provides vibratory feedback and LED indicators on top of hip unit, visible to wearer	Provides visual feedback on the handheld controller and auditory feedback
Fall Detection and Mitigation	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	None
Failsafe Feature	None	In the event of power failure knees become locked and hips free (similar to typical passive leg braces)	In 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 And A1:2012.	ANSI/AAMI ES60601-1:2005/(R)2012	IEC 60601-1:2005 with US deviations
Electromagnetic Compatibility Testing	IEC 60601-1-2:2014	IEC 60601-1-2: 2014	IEC 60601-1-2: 2007

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of Atalante and to show substantial equivalence to the predicate device, Wandercraft SAS completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The Atalante 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 ES60601-1: 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 and there are only two minor unresolved anomalies which do not affect the safety or performance of the device
- 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 43 patients with cerebrovascular accident (CVA) were undertaken. All the subjects that completed the study were able to complete the performance outcome measures. The findings are supported by real world evidence of use by over 250 patients.

There were altogether five adverse events in both clinical studies, none of them serious.

The two clinical studies demonstrated that patients with CVA due to stroke can use the Atalante exoskeleton safely and effectively. Furthermore, the clinical studies indicated that the patient`s functional ambulation abilities and overall balance can be improved by using the Atalante exoskeleton at an early stage of the rehabilitation.

11. Training

Prior to the first use of Atalante, 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 alone with the patient, only after fulfilling all eligibility requirements and pass the certification evaluation.

12. Statement of Substantial Equivalence

The Atalante has the same intended use as the Indego® predicate and Ekso™ (v.1.1)/Ekso GT™ (v.1.2) reference 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 the Atalante is as safe and effective as the predicate device. Therefore, the Atalante is substantially equivalent to the predicate device.