August 3, 2026

Wandercraft SAS
Maria Ida Iacono
Chief of Regulatory, Quality, and Clinical Affairs
88 Rue De Rivoli
Paris, 75004
France

Re: K260381
Trade/Device Name: Eve
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered Lower Extremity Exoskeleton
Regulatory Class: Class II
Product Code: PHL
Dated: July 27, 2026
Received: July 27, 2026

Dear Maria Ida 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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

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. | K260381 |

Please provide the device trade name(s).

Eve

Please provide your Indications for Use below.

Eve - the Personal Exoskeleton by Wandercraft is intended to enable the user to perform walking functions and activities of daily living, hands-free, utilizing self-balancing technology, in home and community settings limited to indoor areas and open-air spaces that are part of a building's structure, under the supervision of a specially trained companion in accordance with the user assessment and training certification program.

Eve is intended to be used by individuals with spinal cord injury at any level, able to operate the device with a controller. The Personal Exoskeleton is intended to be used on individuals of 18 years and older who are able to tolerate a standing position.

Eve is not intended for sports or stair climbing.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

# 510(k) Summary Eve

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: Maria Ida Iacono, PhD
Title: Chief of Regulatory, Quality, and Clinical Affairs - Global

3. **Date Prepared**

August 3, 2026

4. **Device Identification**

| | |
|---|---|
| Trade/Proprietary Name: | Eve |
| 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

| | Predicate Device | Secondary Predicate Device |
|---|---|---|
| Device name | Atalante X | Indego® |
| 510(K) number | K250904 | 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

Eve - the Personal Exoskeleton by Wandercraft - is intended to enable the user to perform walking functions and activities of daily living, hands-free, utilizing self-balancing technology, in home and community settings limited to indoor areas and open-air spaces that are part of a building's structure, under the supervision of a specially trained companion in accordance with the user assessment and training certification program.

Eve is intended to be used by individuals with spinal cord injury at any level, able to operate the device with a controller. The Personal Exoskeleton is intended to be used on individuals of 18 years and older who are able to tolerate a standing position.

Eve is not intended for sports or stair climbing.

## 7. Device Description

Eve - the Personal Exoskeleton by Wandercraft, is a completely self-balancing walking system designed for individuals with mobility impairments. It is a fully powered hip-knee-ankle lower body exoskeleton with 12 actuated degrees of freedom. Eve's self-balancing capability, coupled with dynamic-walking control, facilitates a natural walking pattern.

Eve is designed for personal use on level, firm, dry, smooth walking surfaces only, indoors or in open-air spaces that are part of a building's structure, with the assistance of a companion. It is customized for each user based on morphological dimensions and trajectories which are specifically tuned for the user based on several anatomical measurements.

## 8. Substantial Equivalence Discussion

The following table compares Eve 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 different questions of safety or effectiveness as compared to the predicate.

**Table 1 – Comparison of Characteristics**

| | **Subject Device** | **Predicate Device** | **Secondary Predicate Device** |
|---|---|---|---|
| **FEATURE** | **Eve** | **Atalante X** | **Indego®** |
| 510(k) Number | N/A | K250904 | 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 |
| Intended Use | Facilitate use of the lower extremities in patients with mobility disabilities | Facilitate use of the lower extremities in patients with mobility disabilities | Facilitate use of the lower extremities in patients with mobility disabilities |
| Indications for Use | Eve - the Personal Exoskeleton by Wandercraft is intended to enable the user to perform walking functions and activities of daily living, hands-free, utilizing self-balancing technology, in home and community settings limited to indoor areas and open-air spaces that are part of a building's structure, **under the supervision of a specially trained companion** in accordance with the user assessment and training certification program.<br>Eve is intended to be used by **individuals with spinal cord injury at any level, able to operate the device with a controller.**<br><br>The Personal Exoskeleton is intended to be used on individuals of 18 years and older who are able to tolerate a standing position.<br>Eve 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:<br>**- Individuals with hemiplegia due to cerebrovascular accident (CVA)**<br>**- Individuals with spinal cord injuries at levels C4 to L5 (SCI)**<br>**- Individuals with multiple sclerosis (MS)**<br><br>The operator must complete a training program prior to use of the device.<br>Atalante X is intended to be used on adolescents of 18 years and older, and adults able to tolerate a stand-up position.<br>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 SCI 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.<br>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 | Adolescents of 18 years and older, and adults |

| | | | |
|---|---|---|---|
| Environment | Home and community, on level, firm, dry, smooth walking surfaces only, including indoors areas and open-air spaces that are part of a building's structure, such as an uncovered patio, rooftop terrace, or courtyard. | Rehabilitation institutions | Rehabilitation institutions<br>Home and community |
| 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 | Modular Small, Medium, Large and Extra-Large upper leg, lower leg. Height-adjustable headrest. 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. |
| Control Unit | Control unit integrated into the armrest | Control unit integrated into the torso | Control unit integrated in hip unit |
| 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 | Up to 0.9 km/h | ~2km/h | ~2km/h |
| Type of Surface | Smooth, cement, carpet, tile, door thresholds | Smooth | Smooth, grass, cement, carpet, transitions, thresholds |
| Grade of inclination | Level surfaces | Flat | 5 degrees |
| Range of Motion | Hip: 90° flexion,<br>-20° extension;<br>20° abduction,<br>10° adduction;<br>10° medial rotation,<br>30° lateral rotation<br><br>Knees: 130° Flexion;<br>-5°Extension:<br><br>Ankle: -20° dorsiflexion<br>15° plantar flexion | Hip: 90° flexion,<br>-20° extension;<br>17° abduction,<br>10° adduction;<br>10° medial rotation,<br>20° lateral rotation<br><br>Knee: 110° Flexion;<br>-5°Extension<br><br>Ankle: -20° dorsiflexion,<br>9° plantar flexion | Hips: 110° flexion to 30° extension<br><br>Knees: 110° flexion to 10° extension |
| Device Weight | 183lbs. (83.43 kg) in maximal setting | 176 lbs. (80 kg) | 26 lbs. (12 kg) |
| Rechargeable Battery | Rechargeable Lithium-ion battery. 50.4 V, 18Ah<br><br>Usage duration: 4h of typical use case per charge<br>- Continuous walking for up to 47mn without stopping<br>- Continuous standing for 13mn<br>- Sitting for 180mn | Rechargeable Lithium-ion battery. 46.8 V, 6.4 Ah<br><br>Usage duration: 2h of continuous usage per charge | Rechargeable lithium ion.<br>33.3 V, 36A peak current, 12A continuous current. 159Wh fully charged;<br><br>Usage duration: 1.5h of continuous usage per charge |

| | | | |
|---|---|---|---|
| Battery Charge Time | 4 hours | 2h 30min | 4 hours |
| Training Program | Yes | Yes | Yes |
| Certification Program | Yes | Yes | Yes |
| User Feedback | Provides visual feedback on the hand control, and auditory 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 |
| Fall Detection and Mitigation | Passive hardware protections (headrest with front barrier, armrests, shoulder pads and handle) cushioning and securing the user in case of fall.<br><br>Detects forward, backward and sideways falling as it is happening; the device makes adjustments during the course of the fall to position the user to minimize the risk of injury. | Must be used in combination with safety system | 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 | In the event of a power failure, an automatic descent-control mechanism (called "viscous brakes") engages, enabling the companion to safely control the user's descent to the ground. | (use of a safety system) | In the event of power failure knees become locked and hips free (similar to typical passive leg braces) |
| Electrical safety Testing | IEC 60601-1:2020 + National deviations | ANSI/AAMI ES60601-1:2005/(R)2012 | ANSI/AAMI ES60601-1:2005/(R)2012 |
| Electro-magnetic Compatibility Testing | IEC 60601-1-2: 2020 | IEC 60601-1-2<br>AIM 7351731 | IEC 60601-1-2: 2014 |

**9. Non-Clinical Performance Data**

To demonstrate safety and effectiveness of Eve and to show substantial equivalence to the predicate devices according to the special controls specified in 21 CFR 890.3480, Wandercraft SAS completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. Eve 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:

- Biocompatibility Assessment, including:
  - Cytotoxicity testing per ISO 10993-5: Passed
  - Sensitization testing per ISO 10993-10: Passed

    - Irritation testing per ISO 10993-23: Passed
    - Use of identical skin-contacting materials to predicate device (K250904)
    - Information per *Attachment G: Biocompatibility of Certain Devices in Contact with Intact Skin* of the FDA biocompatibility guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'"
- Electrical safety testing per IEC 60601-1 and 60601-1-11: 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
- Durability Testing and Computational Modeling of Structural Fatigue: Passed
- Fall Protection Testing
- Thermal Testing: Passed
- Useful Life Testing – supports 5 years
- Transportation Testing per ASTM D4169 – demonstrates package integrity is maintained: Passed

**10. Clinical Performance Data**

Three clinical studies in individuals with spinal cord injury (SCI) evaluated the Eve – Personal Exoskeleton in 39 participants with cervical and thoracic injuries (American Spinal Injury Association (ASIA) Impairment Scale (AIS), grades A–D), all able to operate the device using a controller, together with their trained companions. In all studies, participants completed a structured five-session training program followed by functional and usability assessments under representative use conditions. After training, users and companions were able to operate the device safely and effectively as intended. Across the three studies, 25 adverse events considered related or possibly related to the device and/or procedure were reported; all were non-serious and resolved without sequelae. The predefined functional and usability endpoints were met, including a 100% success rate on the co-primary effectiveness measures (Timed Up-and-Go (TUG) test and 6-Minute Walk Test (6MWT)) in the largest study. Overall, these results support that Eve is safe, well-tolerated, and effective for ambulatory activities and functional mobility tasks under the supervision of trained companions, with effectiveness and safety outcomes consistent with those demonstrated for the predicate device Atalante X.

**11. Training**

Prior to the first use of Eve, to ensure safe and effective operation of the device, the users and their companions must complete a certification training.

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. Users and their companions are considered certified, i.e., with proven competence to safely operate Eve, only after fulfilling all eligibility requirements and pass the certification evaluation.

**12. Statement of Substantial Equivalence**

Eve has the same intended use as the predicate devices, Atalante X (K250904) and Indego (K173530), and similar technological characteristics. With respect to indications for use, Eve accommodates a broader SCI population—at any injury level—provided users can operate the controller, thereby extending the indicated SCI population compared with the predicate devices. In addition, Eve is intended for use on level, firm, dry, smooth walking surfaces only, including indoors areas and in open-air spaces that are part of a building's structure, such as an uncovered patio, rooftop terrace, or courtyard, under the supervision of a specially trained companion. Atalante X is limited to use in rehabilitation institutions, whereas Indego is also indicated for use in general community. These differences do not raise new or different questions of safety or effectiveness. Non-clinical performance testing and clinical evidence demonstrate that Eve performs as intended and is as safe and effective as the predicate devices, demonstrating its substantial equivalence.