FDA 510(k) Premarket Notification

K250904 Atalante X

CLEARED

Oct 24, 2025
212 days to decision

K250904 · Product code: **PHL** · Neurology
Source: https://www.510kdatabase.net/k250904/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Exoskeleton (PHL)
Date received	Mar 26, 2025
Decision date	Oct 24, 2025
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wandercraft SAS**
Location	Paris, FR
Contact	Mélanie Combes
510(k) history	3 submissions · 3 cleared · 2022-2025

CLINICAL EVIDENCE - NCT04187209

Evaluation of the Use of the Atalante System in Patients Presenting a Non-traumatic Hemiplegia in Acute-subacute Phase (15 Days to 6 Months).

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	14 patients (actual)
Study sites	3 sites
Condition studied	Stroke; Stroke, Acute; Stroke, Subacute; Robotics
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jan 13, 2021
Sponsor	Wandercraft (Industry)

Primary outcome

Evaluate the use of the Atalante system in patients with non-traumatic acute-subacute hemiplegia over several sessions with a 10 meter Walk Test. This test will show the incidence of test success and emergence of adverse events.

Secondary outcome

Evaluate the patient's ambulatory ability without the Atalante exoskeleton with the Functional Ambulation Classification (FAC).

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04187209