Powered Exoskeletons
Regulatory Background

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Regulatory Definition

Powered Lower Extremity Exoskeleton (21 CFR 890.3480):

Prescription device that is composed of an external, powered, motorized orthosis used for medical purposes that is placed over a person's paralyzed or weakened limbs for the purpose of providing ambulation.

Submission Type: 510(k)

Cleared Devices:

- ReWalk - Argo : De Novo - DEN130034
- Parker Hannifin- Indego: 510(k) - K152416
- Ekso Bionics - Ekso: 510 (k) – K143690 and K161443

Recently Cleared Exoskeleton

ReWalk

Parker Hannifin

Ekso Bionics

Common Device Attributes

- Wearable exoskeleton
- Articulating legs with DC motors at hip and knee joints
- Rechargeable battery
- Requires mobility aid such as crutches, walker, or cane
- Fail safe mode in case of loss of balance or device malfunction
- May include sensors that detect gait initiation and transition
- Wireless/wired control of device modes/parameters by therapist
- Handheld user interface

Indications for Use Summary

	ReWalk DEN130034	Parker Hannifin K152416	Ekso Bionics K143690, K161443
Function	Ambulation Not for sports or stair climbing		
Environment	Rehab Institutes and Community Use	Rehab Institutes and Community Use	Rehab Institutes
Patient Population	SCI: • Community use: T7 - L5 with supervision of a trained companion • Rehab institutes: T4-T6 with supervision of therapist	SCI: • Community use: T7 - L5 with supervision of a trained companion • Rehab institutes: T4-T6 with supervision of therapist	SCI: • T4-L5 • C7-T3 (ASIA D) Hemiplegic
OTC/R_x	R_x	R_x	R_x

Risks

- Instability, falls, and associated Injuries
- Soft tissue injury and pressure sores
- Diastolic hypertension and change in BP and HR
- Adverse tissue reactions
- Premature battery failure
- Interference with other electrical objects
- Burns and electrical shock
- Device malfunctions resulting in unintended movement
- Use Error

Special Controls

- Biocompatibility Assessment
- Electrical, thermal, EMC, battery testing
- Software V&V and hazard analysis
- Design is consistent with intended use
- Mechanical testing:
  - Durability, simulated use, V&V, testing device accuracy and safeguards, flame retardant materials, liquid/particle ingress prevention, sensor and actuator performance, and motor performance
- Clinical testing:
  - Level of supervision necessary, testing in intended use environment with target population
- Training program
- Labeling requirements

Example of Bench Testing

Special Controls	Standard/Testing
Electrical and Thermal Safety	ANSI/AAMI/ES 60601-1
Electromagnetic Compatibility	IEC 60601-1-2
Battery testing	Battery Life Cycle Testing
Durability	Cyclic loading (X cycles @ Maximum BW)
Mechanical Testing	Peak torques applied at joints Shock and impact testing Distribution testing FEA models for component strength
Flammability	ISO 7176
Software Testing	FDA Software Guidance
Biocompatibility	ISO 10993 FDA Biocompatibility Guidance

An exoskeleton standard may…

- Cite parts of current standards that are applicable for exoskeletons
- Provide a consistent framework for battery, durability, and mechanical safety testing.
- Help firms design test methods for outdoor use, including use with environments with water exposure (e.g. rain) and uneven terrain

Example of Clinical Testing

Study Design	Population	Method	Primary Effectiveness Outcomes	Secondary Outcomes	Adverse Events
Open-label, non-comparative, non-randomized	ASIA A-B C7-C8 and T1-T12	90 min sessions for 8 weeks (3X/week);	6MWT 10MWT	Ashworth scale	Hematoma, skin lesions
Open-label, non-comparative, non-randomized	ASIA A-B C7-C8 and T1-T12	90 min sessions for 8 weeks (3X/week);	6MWT 10MWT	Ashworth scale	Skin tears, bruising, blister, lower extremity edema
Pre-post interventional pilot study	Motor-complete T1-T12	1-2 hours for 45±20 sessions (3X/week)	6MWT 10MWT Walking pivot turns	Stopping gait on command, maneuvering, and walking on different surfaces and on stairs	Mild to moderate skin abrasions
Open-label, non-comparative, non-randomized	Ischemic and hemorrhagic stroke	18-25 sessions	6MWT 10MWT FIM Vitals		No falls or adverse events

An exoskeleton standard may..

- Provide framework for measurement of endpoints.
- However, standardization of clinical endpoints may be challenging as clinical testing of the device depends heavily on intended use (population, environment, indications for use)
- Clinical testing, in conjunction with bench testing may be necessary to support safety and effectiveness.


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