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

| Function | Ambulation  
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td></td>
<td>Not for sports or stair climbing</td>
</tr>
</tbody>
</table>
| Environment | Rehab Institutes and Community Use  
| Environment | Rehab Institutes and Community Use  
| Environment | Rehab Institutes  
| Patient Population | SCI: • Community use: T7 - L5 with supervision of a trained companion  
| Patient Population | • Rehab institutes: T4-T6 with supervision of therapist  
| Patient Population | SCI: • Community use: T7 - L5 with supervision of a trained companion  
| Patient Population | • Rehab institutes: T4-T6 with supervision of therapist  
| Patient Population | SCI: • T4-L5  
| Patient Population | • C7-T3 (ASIA D)  
| Patient Population | Hemiplegic  
| OTC/Rₓ | Rₓ  
| OTC/Rₓ | Rₓ  
| OTC/Rₓ | Rₓ  

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*Note: The functions and patient populations listed are indicative of typical use cases and may vary depending on individual circumstances.*
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

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

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