

**K161346 NormaTec PCD-T and PCD-B**Jun 15, 2016  
30 days to decisionK161346 · Product code: **JOW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k161346/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	May 16, 2016
Decision date	Jun 15, 2016
Days to decision	30 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>NormaTec Industries, LP</b>
Location	Washington, DC, US
Contact	Peter Novello
510(k) history	9 submissions · 9 cleared · 2012-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161346/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026