

**K161209 Cirona 6400**May 31, 2016  
33 days to decisionK161209 · Product code: **JOW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k161209/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Apr 28, 2016
Decision date	May 31, 2016
Days to decision	33 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Devon Medical Products</b>
Location	King Of Prussia, PA, US
Contact	ROCCO BRAVOCO
510(k) history	4 submissions · 4 cleared · 2015-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161209/> 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 June 2, 2026