

**K181255 PRODENSE Bone Graft Substitute**Sep 12, 2018  
124 days to decisionK181255 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k181255/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	May 11, 2018
Decision date	Sep 12, 2018
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wrightmedicaltechnologyinc</b>
Location	Arlington, TN, US
Contact	Rachel Roberts
510(k) history	302 submissions · 291 cleared · 1993-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181255/> 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 16, 2026