

**K103064 AVAMAX VERTEBRAL BALLOON**Jan 10, 2011  
84 days to decisionK103064 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k103064/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Oct 18, 2010
Decision date	Jan 10, 2011
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Care Fusion</b>
Location	Waukegan, IL, US
Contact	JOY GREIDANUS
510(k) history	34 submissions · 29 cleared · 2010-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103064/> 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 18, 2026