

**K131820 AVAMAX VERTEBRAL BALLOON SYSTEM, 8G,  
AVAMAX VERTEBRAL BALLOON SYSTEM, 10G, AVAMAX  
VERTEBRAL BALLOON SYSTEM, 11G**Oct 4, 2013  
106 days to decisionK131820 · Product code: **HRX** · Orthopedic  
Source: <https://www.510kdatabase.net/k131820/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Jun 20, 2013
Decision date	Oct 4, 2013
Days to decision	106 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/k131820/> 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 17, 2026