

**K113477 IVAS 20MM (10 GAUGE) BALLOON CATHETER**Jan 6, 2012  
44 days to decisionK113477 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k113477/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Nov 23, 2011
Decision date	Jan 6, 2012
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stryker Instruments, Instruments Div.</b>
Location	Kalamazoo, MI, US
Contact	CHRISTINA MCKEE
510(k) history	6 submissions · 6 cleared · 2007-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113477/> 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