

**K093419 IVAS 2-10MM (10 GAUGE) BALLOON CATHETER,
IVAS 2-15 MM(10 GAUGE)0705-115-500, IVAS 3-10MM(8
GAUGE)BALLOON CATHETER, IVAS**Mar 18, 2010
136 days to decisionK093419 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k093419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Nov 2, 2009
Decision date	Mar 18, 2010
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Instruments, Instruments Div.
Location	Kalamazoo, MI, US
Contact	BECKY E DITTY
510(k) history	6 submissions · 6 cleared · 2007-2013

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