

**K072133 AVAFLEX VERTEBRAL AUGMENTATION NEEDLE**Nov 20, 2007  
110 days to decisionK072133 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k072133/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Aug 2, 2007
Decision date	Nov 20, 2007
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardinal Health, Inc.</b>
Location	Waukegan, IL, US
Contact	SHARON NICHOLS
Website	<a href="http://www.cardinalhealth.com">http://www.cardinalhealth.com</a>
510(k) history	26 submissions · 26 cleared · 2006-2017

Cardinal Health, Inc. is an American multinational health care services company headquartered in Dublin, Ohio. The company specializes in pharmaceutical distribution and medical product manufacturing, serving over 100,000 locations across the United States. Cardinal Health has received FDA 510(k) clearances from total submissions between 2006 and 2017. The company's regulatory focus centers on surgical gloves and protective apparel, including sterile and powder-free formulations. This historical record reflects the company's established presence in General Hospital device...

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