

**K120816 INZONE DETACHMENT SYSTEM**Apr 17, 2012  
29 days to decisionK120816 · Product code: **KRD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k120816/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Mar 19, 2012
Decision date	Apr 17, 2012
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stryker</b>
Location	Portage, MI, US
Contact	MARA CHOU
Website	<a href="http://www.stryker.com/">http://www.stryker.com/</a>
510(k) history	92 submissions · 92 cleared · 2006-2023

Stryker is a family of eight-wheeled armored fighting vehicles derived from the Canadian LAV III. The vehicles are produced by General Dynamics Land Systems-Canada for the United States Army in London, Ontario. This historical record documents FDA 510(k) cleared devices from total submissions between 2006 and 2023. The company's regulatory portfolio focused primarily on General & Plastic Surgery devices, including advanced imaging systems, LED light sources, and surgical visualization equipment. The company has been inactive, with no clearances recorded in more than five ...

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