

**K132947 DIREXION AND DIREXION HI-FLO TORQUEABLE  
MICROCATHETERS**Oct 18, 2013  
29 days to decisionK132947 · Product code: **KRA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k132947/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Continuous Flush (KRA)
Date received	Sep 19, 2013
Decision date	Oct 18, 2013
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific Corp</b>
Location	San Jose, CA, US
Contact	MAUREEN SUNDEEN
Website	<a href="https://www.bostonscientific.com/">https://www.bostonscientific.com/</a>
510(k) history	432 submissions · 411 cleared · 1988-2024

Boston Scientific Corp is a global medical device manufacturer headquartered in San Jose, US. The company develops and markets devices across multiple therapeutic areas including cardiovascular, gastroenterology, and surgical specialties. Boston Scientific has maintained a strong FDA 510(k) regulatory presence since 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2024 demonstrate continued innovation and active market engagement across cardiovascular and gastroenterology device categories. Recent cleared devices reflect th...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k132947/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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