

K142259 Direxion Torqueable MicrocatheterSep 10, 2014
27 days to decisionK142259 · Product code: **KRA** · CardiovascularSource: <https://www.510kdatabase.net/k142259/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Continuous Flush (KRA)
Date received	Aug 14, 2014
Decision date	Sep 10, 2014
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corp
Location	San Jose, CA, US
Contact	Mark Lanz
Website	https://www.bostonscientific.com/
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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142259/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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