

**K132810 GLADIATOR ELITE PTA BALLOON DILATATION CATHETER**Feb 28, 2014  
172 days to decisionK132810 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k132810/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Sep 9, 2013
Decision date	Feb 28, 2014
Days to decision	172 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	BETH TOROK
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/k132810/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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