

**K090554 ACUITY MAILMAN AND STRAIT-TRAK GUIDEWIRE**Jul 2, 2009  
122 days to decisionK090554 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k090554/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Mar 2, 2009
Decision date	Jul 2, 2009
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Boston Scientific Corp</b>
Location	San Jose, CA, US
Contact	STACEY A STRAND
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...

---

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

Device record: <https://www.510kdatabase.net/k090554/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 22, 2026