

**K241227 RHYTHMIA HDx™ Mapping System**Aug 29, 2024  
119 days to decisionK241227 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k241227/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	May 2, 2024
Decision date	Aug 29, 2024
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific Corporation</b>
Location	Marlborough, MA, US
Contact	Liliana Omar
Website	<a href="https://www.bostonscientific.com">https://www.bostonscientific.com</a>
510(k) history	229 submissions · 216 cleared · 2005-2026

Boston Scientific Corporation is a global medical device manufacturer headquartered in Marlborough, Massachusetts. The company develops and markets devices across multiple medical specialties. Boston Scientific has received FDA 510(k) clearances from total submissions since its first clearance in 2005. The company maintains active regulatory engagement, with the latest clearance in 2026. Its cleared devices span cardiovascular, radiology, gastroenterology, urology, and surgical specialties, reflecting a broad portfolio of interventional and diagnostic technologies. Recent...

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

Device record: <https://www.510kdatabase.net/k241227/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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