

**K231328 LUX-Dx II (M302)**Aug 19, 2023  
103 days to decisionK231328 · Product code: **MXD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k231328/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Event, Implantable Cardiac, (with Arrhythmia Detection) (MXD)
Date received	May 8, 2023
Decision date	Aug 19, 2023
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	LUX-Dx II+ (M312)

**APPLICANT**

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Company	<b>Boston Scientific Corp</b>
Location	San Jose, CA, US
Contact	Melissa Klamerus
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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