

**K252593 LUX-Dx II Insertable Cardiac Monitor (M302)**Sep 12, 2025  
28 days to decisionK252593 · Product code: **MXD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k252593/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Event, Implantable Cardiac, (with Arrhythmia Detection) (MXD)
Date received	Aug 15, 2025
Decision date	Sep 12, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	LUX-Dx II+ Insertable Cardiac Monitor (M312)

**APPLICANT**

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Company	<b>Boston Scientific Corporation</b>
Location	Marlborough, MA, US
Contact	Emily Bailey
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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