

# K193473 LUX-Dx Insertable Cardiac Monitor, myLUX Software Mobile Application, LUX-Dx Clinic Assistant Software, Application Server Device Services (DS) - US

Jun 26, 2020  
193 days to decision

K193473 · Product code: **MXD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k193473/>

## 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	Dec 16, 2019
Decision date	Jun 26, 2020
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Boston Scientific Corporation</b>
Location	Marlborough, MA, US
Contact	Melissa Klamerus
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...