

**K010634 HEARTSTREAM XL DEFIBRILLATOR/MONITOR,  
MODEL M4735A, HEARTSTREAM XLT  
DEFIBRILLATOR/MONITOR.MODEL M2500B**Jun 11, 2001  
101 days to decisionK010634 · Product code: **MKJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k010634/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Mar 2, 2001
Decision date	Jun 11, 2001
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Agilent Technologies, Inc.</b>
Location	Pittsburgh, PA, US
Contact	RICHARD J PETERSEN
Website	<a href="http://www.agilent.com">http://www.agilent.com</a>
510(k) history	30 submissions · 30 cleared · 1985-2017

Agilent Technologies, Inc. is an American global company that provides instruments, software, services, and consumables for laboratories. Headquartered in Santa Clara, California, Agilent was established in 1999 as a spin-off from Hewlett-Packard. The company has received FDA 510(k) clearances from total submissions. Cardiovascular devices represent the dominant focus, accounting for approximately 80% of regulatory submissions. Agilent's FDA 510(k) clearance history spans from 1985 to 2017, establishing a long track record in medical device regulation. Notable cleared dev...