FDA 510(k) Premarket Notification

CLEARED

K001725 HEARTSTREAM XL DEFIBRILLATOR/MONITOR, MODEL M4735A

Sep 8, 2000
94 days to decision

K001725 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k001725/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Jun 6, 2000
Decision date	Sep 8, 2000
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Agilent Technologies, Inc.**
Location	Pittsburgh, PA, US
Contact	RICHARD J PETERSEN
Website	http://www.agilent.com
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...