CLEARED

K001057 AGILENT INFORMATION CENTER SOFTWARE FOR M3150A AND M3153A AND AGILENT M2/M3/M4 COMPACT PORTABLE PATIENT MONITOR

May 3, 2000
30 days to decision

K001057 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k001057/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Apr 3, 2000
Decision date	May 3, 2000
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Agilent Technologies, Inc.**
Location	Pittsburgh, PA, US
Contact	DAVE OSBORN
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...