FDA 510(k) Premarket Notification

CLEARED

K011093 AGILENT INFORMATION CENTER SOFTWARE FOR M3150,M3151,M3153 AND M3154

May 1, 2001
21 days to decision

K011093 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k011093/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 10, 2001
Decision date	May 1, 2001
Days to decision	21 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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k011093/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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