FDA 510(k) Premarket Notification

CLEARED

K001664 COMPACT PORTABLE PATIENT MONITOR WITH WIRELESS ALAN, MODEL ALILENT M3000A/M3046A OPTION J120

Jun 30, 2000
30 days to decision

K001664 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k001664/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	May 31, 2000
Decision date	Jun 30, 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...