FDA 510(k) Premarket Notification

CLEARED

K012094 MODIFICATION TO DEVICE LINK SYSTEM, MODEL M2376A

Jul 20, 2001
15 days to decision

K012094 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k012094/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jul 5, 2001
Decision date	Jul 20, 2001
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Agilent Technologies, Inc.**
Location	Pittsburgh, PA, US
Contact	MIKE HUDON
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...