FDA 510(k) Premarket Notification

**CLEARED**

# K011824 AGILENT M2636B TELEMON B MONITOR (TELEMON B)

Jul 2, 2001
21 days to decision

K011824 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k011824/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Detector And Alarm, Arrhythmia (DSI) |
| Date received | Jun 11, 2001 |
| Decision date | Jul 2, 2001 |
| Days to decision | 21 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Agilent Technologies, Inc.** |
| Location | Pittsburgh, PA, US |
| Contact | DENISE HALEY |
| 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...