

K972991 MONITOR ONE NDXDec 3, 1998
478 days to decisionK972991 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k972991/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Aug 12, 1997
Decision date	Dec 3, 1998
Days to decision	478 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Qmed, Inc.
Location	Mchenry, IL, US
Contact	JOSEPH HANNA
510(k) history	11 submissions · 11 cleared · 1984-1998

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