

K251591 Holter ECG and ABP system (HolterABP)Feb 9, 2026
262 days to decisionK251591 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k251591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	May 23, 2025
Decision date	Feb 9, 2026
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Edan Instruments, Inc.
Location	Shenzhen, CN
Contact	Tracy Yue
Website	https://www.edan.com.cn
510(k) history	92 submissions · 92 cleared · 2004-2026

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