

K230184 Holter ECG and ABP SystemSep 25, 2023
245 days to decisionK230184 · Product code: **DSH** · CardiovascularSource: <https://www.510kdatabase.net/k230184/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Jan 23, 2023
Decision date	Sep 25, 2023
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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