

K110328 ACG-8511 PORTABLE ECG MONITORJul 15, 2011
162 days to decisionK110328 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k110328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Feb 3, 2011
Decision date	Jul 15, 2011
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Andon Health Co, Ltd.
Location	Tiajin, CN
Contact	LIU YI
510(k) history	92 submissions · 92 cleared · 2008-2025

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