

K131262 DIGITAL ELECTROCARDIOGRAPHSNov 14, 2013
195 days to decisionK131262 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k131262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	May 3, 2013
Decision date	Nov 14, 2013
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sonoscape Company Limited
Location	Dublin, CA, US
Contact	Diana Hong
510(k) history	22 submissions · 22 cleared · 2004-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131262/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026