FDA 510(k) Premarket Notification

K131262 DIGITAL ELECTROCARDIOGRAPHS

CLEARED

Nov 14, 2013
195 days to decision

K131262 · 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