

K181998 CardioBand ECG Event RecorderNov 15, 2018
112 days to decisionK181998 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k181998/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jul 26, 2018
Decision date	Nov 15, 2018
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Samsung Strategy and Innovation Center (Ssic)
Location	San Jose, CA, US
Contact	Bhupinder Singh
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181998/> 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 June 28, 2026