

K173461 ECG recorder and Arrhythmia DetectorAug 3, 2018
269 days to decisionK173461 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k173461/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Nov 7, 2017
Decision date	Aug 3, 2018
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smart Solutions Technologies SL
Location	Madrid, ES
Contact	Daniel Llorca
510(k) history	2 submissions · 2 cleared · 2018-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173461/> 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 27, 2026