

K092576 GEM HEART ONE/ONE+Sep 4, 2009
14 days to decisionK092576 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k092576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Aug 21, 2009
Decision date	Sep 4, 2009
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Gem-Med S.L.
Location	Barcelona, ES
Contact	WILSON TSENG
510(k) history	1 submissions · 1 cleared · 2009-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092576/> 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 22, 2026