

K152612 eSensor Warfarin Sensitivity Saliva TestMay 26, 2016
255 days to decisionK152612 · Product code: **ODW** · Chemistry
Source: <https://www.510kdatabase.net/k152612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cytochrome P450 2c9 (cyp450 2c9) Drug Metabolizing Enzyme Genotyping System (ODW)
Date received	Sep 14, 2015
Decision date	May 26, 2016
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genmark Diagnostics, Incorporated
Location	Carlsbad, CA, US
Contact	ALAN MADERAZO
510(k) history	7 submissions · 7 cleared · 2016-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152612/> 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