

K101683 INFINITI CYP2C19 ASSAYOct 25, 2010
132 days to decisionK101683 · Product code: **NTI** · Toxicology
Source: <https://www.510kdatabase.net/k101683/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Drug Metabolizing Enzyme Genotyping Systems (NTI)
Date received	Jun 15, 2010
Decision date	Oct 25, 2010
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Autogenomics, Incorporated
Location	Carlsbad, CA, US
Contact	EVELYN G LOPEZ
510(k) history	2 submissions · 2 cleared · 2008-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101683/> 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 20, 2026