

K122291 THERMO SCIENTIFIC MAS OMNI-CARDIOAug 31, 2012
31 days to decisionK122291 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k122291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Jul 31, 2012
Decision date	Aug 31, 2012
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Microgenics Corporation
Location	Fremont Blvd., CA, US
Contact	KAREN LEE
510(k) history	21 submissions · 20 cleared · 2009-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122291/> 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 13, 2026