

K131584 IMDX FLU A/B AND RSV FOR ABBOTT M2000Aug 21, 2013
82 days to decisionK131584 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k131584/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	May 31, 2013
Decision date	Aug 21, 2013
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intelligent Medical Devices, Inc.
Location	Beverly, MA, US
Contact	FRAN WHITE
510(k) history	4 submissions · 4 cleared · 2013-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131584/> 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 14, 2026