

K993323 K-ASSAY IGMNov 30, 1999
57 days to decisionK993323 · Product code: **CFF** · Immunology
Source: <https://www.510kdatabase.net/k993323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immuno-electrophoretic, Immunoglobulins, (g, A, M) (CFF)
Date received	Oct 4, 1999
Decision date	Nov 30, 1999
Days to decision	57 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Kamiya Biomedical Co.
Location	Thousand Oaks, CA, US
Contact	COLIN GETTY
510(k) history	43 submissions · 43 cleared · 1991-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k993323/> 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