

**K090236 DIMENSION VISTA AFP FLEX REAGENT CARTRIDGE,
MODEL 6454**

Apr 27, 2009
84 days to decision

K090236 · Product code: **LOJ** · Immunology
Source: <https://www.510kdatabase.net/k090236/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test,alpha-fetoprotein For Testicular Cancer (LOJ)
Date received	Feb 2, 2009
Decision date	Apr 27, 2009
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	JANET M FOSE
510(k) history	92 submissions · 92 cleared · 2008-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k090236/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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