

**K982251 SIGMA DIAGNOSTICS INFINITY URIC ACID REAGENT
KIT**Aug 18, 1998
53 days to decisionK982251 · Product code: **CDO** · Chemistry
Source: <https://www.510kdatabase.net/k982251/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Uric, Uricase (u.v.) (CDO)
Date received	Jun 26, 1998
Decision date	Aug 18, 1998
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
510(k) history	164 submissions · 164 cleared · 1984-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982251/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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