

K971405 SPECIALITY URINE 1,2Jun 16, 1997
61 days to decisionK971405 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k971405/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Apr 16, 1997
Decision date	Jun 16, 1997
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Chiron Diagnostics Corp.
Location	Medfield, MA, US
Contact	RONALD D SCHAEFER
510(k) history	20 submissions · 20 cleared · 1997-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971405/> 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 28, 2026