

K001651 BIO-RAD %CDT TIANov 22, 2000
176 days to decisionK001651 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k001651/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	May 30, 2000
Decision date	Nov 22, 2000
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Axis-Shield Biochemicals, Asa
Location	San Diego, CA, US
Contact	RONALD G LEONARDI
510(k) history	2 submissions · 2 cleared · 2000-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001651/> 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