

K903235 STATLAB A-350 SALIVA ALCOHOL TESTOct 12, 1990
81 days to decisionK903235 · Product code: **DIC** · Toxicology
Source: <https://www.510kdatabase.net/k903235/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alcohol Dehydrogenase, Specific Reagent For Ethanol Enzyme Method (DIC)
Date received	Jul 23, 1990
Decision date	Oct 12, 1990
Days to decision	81 days
Third-party review	No

APPLICANT

Company	Enzymatics C/O Burditt,Bowles,Radzius & Ruberry
Location	Horsham, PA, US
Contact	CHRISTOPER ZALESKY
510(k) history	3 submissions · 3 cleared · 1990-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k903235/>; 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 29, 2026