

K894001 SALIVA ALCOHOL TESTApr 5, 1990
304 days to decisionK894001 · Product code: **DIC** · Chemistry
Source: <https://www.510kdatabase.net/k894001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alcohol Dehydrogenase, Specific Reagent For Ethanol Enzyme Method (DIC)
Date received	Jun 5, 1989
Decision date	Apr 5, 1990
Days to decision	304 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k894001/>, 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