



## CLIA record **K894001** and corresponding 510(K) Premarket Notification information

**Test System Name** STC TECHNOLOGIES ORASURE Q.E.D. A-150 SALIVA ALCOHOL TEST  
**Document Number** K894001  
**Analyte Name** ALCOHOL, SALIVA  
**Analyte Specialty** Toxicology / TDM  
**Complexity** WAIVED

**Effective Date** 01/22/2001

This complexity categorization is effective as of the *Effective Date* noted above. This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte(s) indicated. This categorization will also be announced in a Federal Register Notice which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice. For questions regarding FDA's categorization procedure, email [clia@cdrh.fda.gov](mailto:clia@cdrh.fda.gov)

### 510(k) Premarket Notification Database

<b>Device Classification Name</b>	<a href="#">alcohol dehydrogenase, specific reagent for ethanol enzyme method</a>
<b>510(k) Number</b>	K894001
<b>Regulation Number</b>	<a href="#">862.3040</a>
<b>Device Name</b>	SALIVA ALCOHOL TEST
<b>Applicant</b>	ENZYMATICS C/O BURDITT,BOWLES,RADZIUS & RUBERRY 355 business center dr. horsham, PA 19044
<b>Contact</b>	christopher zalesky
<b>Product Code</b>	DIC
<b>Date Received</b>	06/05/1989
<b>Decision Date</b>	04/05/1990
<b>Decision</b>	substantially equivalent (SE)
<b>Classification Advisory Committee</b>	Toxicology
<b>Review Advisory Committee</b>	Clinical Chemistry
<b>Statement/Summary/Purged Status</b>	Purged, no summary or statement
<b>Type</b>	Traditional
<b>Reviewed by Third Party</b>	No

Database Updated 11/05/2004