

**K970357 EPISCREEN**Mar 10, 1997  
39 days to decisionK970357 · Product code: **PJD** · Microbiology  
Source: <https://www.510kdatabase.net/k970357/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oral Fluid Drugs Of Abuse And Alcohol Test Specimen Collection Device (PJD)
Date received	Jan 30, 1997
Decision date	Mar 10, 1997
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Epitope, Inc.</b>
Location	Beaverton, OR, US
Contact	CAROLINE R SAYRE, RAC
510(k) history	2 submissions · 2 cleared · 1997-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970357/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026