

**K954264 ACI SINGLE LUMEN BIOPSY NEEDLE**Nov 29, 1995  
78 days to decisionK954264 · Product code: **BTA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k954264/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Portable, Aspiration (manual Or Powered) (BTA)
Date received	Sep 12, 1995
Decision date	Nov 29, 1995
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Advanced Cytometrix, Inc.</b>
Location	Sunnyvale, CA, US
Contact	DEEPAK GHANDI
510(k) history	3 submissions · 3 cleared · 1995-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954264/> 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 July 5, 2026