

**K941549 BIOPSY NEEDLE AND HOUSING**Apr 19, 1994  
20 days to decisionK941549 · Product code: **KNW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k941549/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Mar 30, 1994
Decision date	Apr 19, 1994
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biopsys Medical, Inc.</b>
Location	San Juan Capistrano, CA, US
Contact	MARK A COLE
510(k) history	15 submissions · 15 cleared · 1994-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k941549/> 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 May 20, 2026