

**K964777 TZ**Jan 3, 1997  
37 days to decisionK964777 · Product code: **KNW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k964777/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Nov 27, 1996
Decision date	Jan 3, 1997
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gallini Intl., Inc.</b>
Location	Cliffside Park, NJ, US
Contact	PAUL L HAWTHORNE
510(k) history	7 submissions · 7 cleared · 1996-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964777/> 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 1, 2026