

**K990716 GALLINI BYCUT NEEDLE**May 17, 1999  
74 days to decisionK990716 · Product code: **KNW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k990716/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Mar 4, 1999
Decision date	May 17, 1999
Days to decision	74 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Gallini U.S., LLC</b>
Location	Glen Allen, VA, US
Contact	PAUL L HAWTHORNE
510(k) history	10 submissions · 10 cleared · 1997-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k990716/> 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