

**K981301 SPEED-CUT AUTOMATIC BIOPSY SYSTEM**Jul 8, 1998  
90 days to decisionK981301 · Product code: **KNW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k981301/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Apr 9, 1998
Decision date	Jul 8, 1998
Days to decision	90 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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