

K974440 IBIJan 30, 1998
66 days to decisionK974440 · Product code: **KNW** · Gastroenterology & Urology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Nov 25, 1997
Decision date	Jan 30, 1998
Days to decision	66 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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