

K970871 TR NEEDLEMay 21, 1997
72 days to decisionK970871 · Product code: **KNW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k970871/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Mar 10, 1997
Decision date	May 21, 1997
Days to decision	72 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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