

**K971842 COAXIAL NEEDLE**Jun 20, 1997  
32 days to decisionK971842 · Product code: **FCG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k971842/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	May 19, 1997
Decision date	Jun 20, 1997
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>United States Endoscopy Group, Inc.</b>
Location	Mentor, OH, US
Contact	GRETCHEN Y COHEN
510(k) history	94 submissions · 92 cleared · 1991-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971842/> 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 June 15, 2026