

K012358 CHIBA NEEDLEOct 15, 2001
82 days to decisionK012358 · Product code: **FCG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k012358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Jul 25, 2001
Decision date	Oct 15, 2001
Days to decision	82 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ispg, Inc.
Location	New Milford, CT, US
Contact	LORETTA F LUHMAN
510(k) history	4 submissions · 4 cleared · 1995-2001

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