

K854404 ROTEX SCREW BIOPSY NEEDLEDec 2, 1985
31 days to decisionK854404 · Product code: **FCG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k854404/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Nov 1, 1985
Decision date	Dec 2, 1985
Days to decision	31 days
Third-party review	No

APPLICANT

Company	Madox Surgimed, Inc.
Location	Mchenry, IL, US
Contact	SCOTT MINDREBO
510(k) history	24 submissions · 24 cleared · 1984-1995

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