

K954596 PRO-B CORE-RECT COAXIAL BIOPSY SYSTEMOct 7, 1995
4 days to decisionK954596 · Product code: **FCG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k954596/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Oct 3, 1995
Decision date	Oct 7, 1995
Days to decision	4 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Promedical , Ltd.
Location	Wyckoff, NJ, US
Contact	HENRY V SIERAKOWSKI
510(k) history	5 submissions · 5 cleared · 1994-1995

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