

**K954231 AUGASTROENTEROLOGY-UROLOGY BIOPSY
INSTRUMENT**Sep 22, 1995
11 days to decisionK954231 · Product code: **FCG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k954231/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Sep 11, 1995
Decision date	Sep 22, 1995
Days to decision	11 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Promex, Inc.
Location	Indianapolis, IN, US
Contact	JOSEPH L MARK
510(k) history	18 submissions · 18 cleared · 1994-2002

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