

**K945146 CHIBA, FRANSEEN, WESTCOTT, SPINAL STYLE  
ASPIRATION BIOPSY NEEDLE**Dec 21, 1994  
62 days to decisionK945146 · Product code: **FCG** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k945146/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Oct 20, 1994
Decision date	Dec 21, 1994
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945146/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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