

K951598 PRO-B BIOPSY NEEDLEApr 21, 1995
14 days to decisionK951598 · Product code: **FCG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k951598/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Apr 7, 1995
Decision date	Apr 21, 1995
Days to decision	14 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951598/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 1, 2026