FDA 510(k) Premarket Notification

K951598 PRO-B BIOPSY NEEDLE

CLEARED

Apr 21, 1995
14 days to decision

K951598 · Product code: **FCG** · Gastroenterology & Urology
Source: 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