FDA 510(k) Premarket Notification

K890327 BIOPSY NEEDLE GUIDE ATTACHMENT

CLEARED

Mar 8, 1989
44 days to decision

K890327 · Product code: **FCG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k890327/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Jan 23, 1989
Decision date	Mar 8, 1989
Days to decision	44 days
Third-party review	No

APPLICANT

Company	**Elscint, Inc.**
Location	Mchenry, IL, US
Contact	ROBERT E KENNEY
510(k) history	94 submissions · 94 cleared · 1981-1998