FDA 510(k) Premarket Notification

K971842 COAXIAL NEEDLE

CLEARED

Jun 20, 1997
32 days to decision

K971842 · Product code: **FCG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k971842/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	May 19, 1997
Decision date	Jun 20, 1997
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**United States Endoscopy Group, Inc.**
Location	Mentor, OH, US
Contact	GRETCHEN Y COHEN
510(k) history	94 submissions · 92 cleared · 1991-2020