FDA 510(k) Premarket Notification

K950810 RUTNER BIOPSY DEVICE

CLEARED

Mar 6, 1995
12 days to decision

K950810 · Product code: **FCG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k950810/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Feb 22, 1995
Decision date	Mar 6, 1995
Days to decision	12 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cook Urological, Inc.**
Location	Spencer, IN, US
Contact	TAMMY BACON
510(k) history	104 submissions · 102 cleared · 1986-2011