

**K950810 RUTNER BIOPSY DEVICE**Mar 6, 1995  
12 days to decisionK950810 · Product code: **FCG** · Gastroenterology & UrologySource: <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	<b>Cook Urological, Inc.</b>
Location	Spencer, IN, US
Contact	TAMMY BACON
510(k) history	104 submissions · 102 cleared · 1986-2011

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950810/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 19, 2026