

**K972266 GALLINI COAXIAL INTRODUCER**Jul 29, 1997  
42 days to decisionK972266 · Product code: **KNW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k972266/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jun 17, 1997
Decision date	Jul 29, 1997
Days to decision	42 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Gallini U.S., LLC</b>
Location	Glen Allen, VA, US
Contact	PAUL L HAWTHORNE
510(k) history	10 submissions · 10 cleared · 1997-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972266/> 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 July 1, 2026