FDA 510(k) Premarket Notification

K980676 SPIGAL NEEDLE

CLEARED

May 21, 1998
90 days to decision

K980676 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k980676/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Feb 20, 1998
Decision date	May 21, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k980676/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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