FDA 510(k) Premarket Notification

K972266 GALLINI COAXIAL INTRODUCER

CLEARED

Jul 29, 1997
42 days to decision

K972266 · 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	**Gallini U.S., LLC**
Location	Glen Allen, VA, US
Contact	PAUL L HAWTHORNE
510(k) history	10 submissions · 10 cleared · 1997-1999