FDA 510(k) Premarket Notification

K990716 GALLINI BYCUT NEEDLE

CLEARED

May 17, 1999
74 days to decision

K990716 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k990716/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Mar 4, 1999
Decision date	May 17, 1999
Days to decision	74 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