FDA 510(k) Premarket Notification

K950125 KARL STORZ BOUGIES AND DILATORS

CLEARED

Feb 7, 1995
26 days to decision

K950125 · Product code: **FAX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k950125/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bougie, Urological (FAX)
Date received	Jan 12, 1995
Decision date	Feb 7, 1995
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**KARL STORZ Endoscopy-America, Inc.**
Location	Mchenry, IL, US
Contact	BETTY M JOHNSON
510(k) history	361 submissions · 361 cleared · 1980-2024