FDA 510(k) Premarket Notification

K965199 TUNA 5 CATHETER

CLEARED

Apr 30, 1997
125 days to decision

K965199 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k965199/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 26, 1996
Decision date	Apr 30, 1997
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vidamed, Inc.**
Location	Menlo Park, CA, US
Contact	NOEL MESSENGER
510(k) history	11 submissions · 11 cleared · 1995-2002