FDA 510(k) Premarket Notification

K934391 V/P AND L/P CATHETER PASSERS

CLEARED

Nov 19, 1993
71 days to decision

K934391 · Product code: **GYK** · Neurology
Source: https://www.510kdatabase.net/k934391/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Shunt System Implantation (GYK)
Date received	Sep 9, 1993
Decision date	Nov 19, 1993
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Radionics, Inc.**
Location	Walker, MI, US
Contact	LINDA JALBERT
510(k) history	56 submissions · 56 cleared · 1982-2003