FDA 510(k) Premarket Notification

K970983 PERITONEAL/CARDIAC CATHETER

CLEARED

Jun 13, 1997
87 days to decision

K970983 · Product code: **JXG** · Neurology
Source: https://www.510kdatabase.net/k970983/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Mar 18, 1997
Decision date	Jun 13, 1997
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Integra Neurocare, LLC**
Location	San Diego, CA, US
Contact	LORI L HAYS
510(k) history	12 submissions · 12 cleared · 1996-2000