

K970983 PERITONEAL/CARDIAC CATHETERJun 13, 1997
87 days to decisionK970983 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970983/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026