

K972261 RIVETTI-LEVINSON INSTRALUMINAL SHUNTSep 15, 1997
90 days to decisionK972261 · Product code: **DWF** · CardiovascularSource: <https://www.510kdatabase.net/k972261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Jun 17, 1997
Decision date	Sep 15, 1997
Days to decision	90 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/k972261/> 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