FDA 510(k) Premarket Notification

K972261 RIVETTI-LEVINSON INSTRALUMINAL SHUNT

CLEARED

Sep 15, 1997
90 days to decision

K972261 · Product code: **DWF** · Cardiovascular
Source: 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