FDA 510(k) Premarket Notification

K812539 PRE-BYPASS FILTER

CLEARED

Oct 13, 1981
40 days to decision

K812539 · Product code: **KRJ** · Cardiovascular
Source: https://www.510kdatabase.net/k812539/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Prebypass, Cardiopulmonary Bypass (KRJ)
Date received	Sep 3, 1981
Decision date	Oct 13, 1981
Days to decision	40 days
Third-party review	No

APPLICANT

Company	**Gelman Sciences, Inc.**
Location	Mchenry, IL, US
510(k) history	32 submissions · 32 cleared · 1979-1995