FDA 510(k) Premarket Notification

K780485 PREBYPASS FILTER

CLEARED

Apr 5, 1978
9 days to decision

K780485 · Product code: **KRJ** · Cardiovascular
Source: https://www.510kdatabase.net/k780485/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Prebypass, Cardiopulmonary Bypass (KRJ)
Date received	Mar 27, 1978
Decision date	Apr 5, 1978
Days to decision	9 days
Third-party review	No

APPLICANT

Company	**Delta Medical Industries**
Location	Mchenry, IL, US
510(k) history	27 submissions · 27 cleared · 1976-1984