FDA 510(k) Premarket Notification

K803101 PREBYPASS FILTER CAT.#K-5

CLEARED

Dec 22, 1980
13 days to decision

K803101 · Product code: **KRJ** · Cardiovascular
Source: https://www.510kdatabase.net/k803101/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Prebypass, Cardiopulmonary Bypass (KRJ)
Date received	Dec 9, 1980
Decision date	Dec 22, 1980
Days to decision	13 days
Third-party review	No

APPLICANT

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