FDA 510(k) Premarket Notification

K810395 PRE-BYPASS FILTER

CLEARED

Mar 5, 1981
15 days to decision

K810395 · Product code: **KRJ** · Cardiovascular
Source: https://www.510kdatabase.net/k810395/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Prebypass, Cardiopulmonary Bypass (KRJ)
Date received	Feb 18, 1981
Decision date	Mar 5, 1981
Days to decision	15 days
Third-party review	No

APPLICANT

Company	**Texas Medical Products, Inc.**
Location	Mchenry, IL, US
510(k) history	30 submissions · 30 cleared · 1980-1989

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k810395/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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