FDA 510(k) Premarket Notification

K030398 CARDIACASSIST TRANSSEPTAL CANNULA SET, MODEL 5132-6221

CLEARED

May 23, 2003
106 days to decision

K030398 · Product code: **DQR** · Cardiovascular
Source: https://www.510kdatabase.net/k030398/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Catheter (DQR)
Date received	Feb 6, 2003
Decision date	May 23, 2003
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiacassist, Inc.**
Location	Pittsburgh, PA, US
Contact	TIM KRAUSKOPF
510(k) history	21 submissions · 21 cleared · 2000-2024