FDA 510(k) Premarket Notification

K973298 CARDIMA VUEPORT CORONARY SINUS BALLOON OCCLUSION GUIDING CATHETER

CLEARED

Jun 26, 1998
297 days to decision

K973298 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k973298/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 2, 1997
Decision date	Jun 26, 1998
Days to decision	297 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardima, Inc.**
Location	Fremont, CA, US
Contact	SHELLEY TRIMM
510(k) history	12 submissions · 12 cleared · 1993-2006