FDA 510(k) Premarket Notification

K012325 CARDIOVENTION CORX SYSTEM, MODEL FG 0001

CLEARED

Apr 9, 2002
260 days to decision

K012325 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k012325/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Jul 23, 2001
Decision date	Apr 9, 2002
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiovention, Inc.**
Location	Santa Clara, CA, US
Contact	TESSA YAMUT
510(k) history	4 submissions · 4 cleared · 2002-2003