FDA 510(k) Premarket Notification

CLEARED

K912604 SJM/CAD ISOFLOW(TM) CENTRIFUGAL PUMP 2100CP, MODIF

Oct 28, 1991
150 days to decision

K912604 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k912604/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	May 31, 1991
Decision date	Oct 28, 1991
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aries Medical, Inc.**
Location	Walker, MI, US
Contact	JOSEPH CURTIS
510(k) history	19 submissions · 18 cleared · 1984-1991