FDA 510(k) Premarket Notification

K972740 HIMEX CENTRIFLOW CENTRIFUGAL PERFUSION PUMP SYSTEM (CFK01)

CLEARED

Feb 6, 1998
199 days to decision

K972740 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k972740/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Jul 22, 1997
Decision date	Feb 6, 1998
Days to decision	199 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Himex Production Corp.**
Location	Houston, TX, US
Contact	GREG GEORGES
510(k) history	1 submissions · 1 cleared · 1998-1998