FDA 510(k) Premarket Notification

K962981 CAPIOX SP PUMP HEAD

CLEARED

Feb 25, 1997
208 days to decision

K962981 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k962981/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Aug 1, 1996
Decision date	Feb 25, 1997
Days to decision	208 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Terumo Medical Corp.**
Location	Elkton, MD, US
Contact	SANDI HARTKA
510(k) history	143 submissions · 143 cleared · 1980-2011