FDA 510(k) Premarket Notification

K083794 MECC SET WITH BIOLINE COATING

CLEARED

Apr 21, 2009
120 days to decision

K083794 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k083794/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Dec 22, 2008
Decision date	Apr 21, 2009
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Maquet Cardiopulmonary, AG**
Location	Fairfield, IA, US
Contact	KATRIN SCHWENKGLENKS
510(k) history	44 submissions · 44 cleared · 2005-2015