FDA 510(k) Premarket Notification

CLEARED

K133265 QUADROX-IR ADULT AND SMALL ADULT

Nov 12, 2013
20 days to decision

K133265 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k133265/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Oct 23, 2013
Decision date	Nov 12, 2013
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k133265/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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