FDA 510(k) Premarket Notification

CLEARED

K132829 QUADROX-I, QUADROX-ID, QUADROX-IR OXYGENATORS

Oct 8, 2013
29 days to decision

K132829 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k132829/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Sep 9, 2013
Decision date	Oct 8, 2013
Days to decision	29 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