

**K103191 QUADROX-I PEDIATRIC MICROPOROUS MEMBRANE
OXYGENATOR WITH INTEGRATED ARTERIAL FILTER WITH
SOFTLINE / BIOLINE COATING**Mar 8, 2011
131 days to decisionK103191 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k103191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Oct 28, 2010
Decision date	Mar 8, 2011
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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