

**K061628 JOSTRA QUADROX D SAFELINE DIFFUSION  
MEMBRANE OXYGENATOR, MODEL HMOD 2030**Aug 22, 2006  
71 days to decisionK061628 · Product code: DTZ · Cardiovascular  
Source: <https://www.510kdatabase.net/k061628/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jun 12, 2006
Decision date	Aug 22, 2006
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Maquet Cardiopulmonary, AG</b>
Location	Fairfield, IA, US
Contact	JAMES COLLIE
510(k) history	44 submissions · 44 cleared · 2005-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061628/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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