

**K030264 QUANDROX SAFELINE HOLLOW FIBER MEMBRANE
OXYGENATOR, MODEL HMO 2030**Feb 26, 2003
30 days to decisionK030264 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k030264/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jan 27, 2003
Decision date	Feb 26, 2003
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Jostra AG
Location	Newark, DE, US
Contact	KATRIN SCHWENKGLLENKS
510(k) history	13 submissions · 13 cleared · 2000-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k030264/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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