

**K070320 EDWARDS AQUARIUS HEMOFILTRATION SYSTEM,
MODEL ABM 01**Jun 7, 2007
125 days to decisionK070320 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k070320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Feb 2, 2007
Decision date	Jun 7, 2007
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences Services GmbH
Location	Stevenage, GB
Contact	NEIL R ARMSTRONG
510(k) history	3 submissions · 3 cleared · 2007-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k070320/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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