

**K082117 QUADROX-I ADULT WITH AND WITHOUT  
INTEGRATED ARTERIAL FILTER WITH SOFTLINE COATING,  
MODEL# HMO 70000, HMO 71000**Feb 18, 2009  
205 days to decisionK082117 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k082117/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jul 28, 2008
Decision date	Feb 18, 2009
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082117/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 4, 2026