

K100905 HYDROFIX SURGICAL SHEETJun 2, 2010
62 days to decisionK100905 · Product code: **OMR** · Cardiovascular
Source: <https://www.510kdatabase.net/k100905/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Vessel Guard Or Cover (OMR)
Date received	Apr 1, 2010
Decision date	Jun 2, 2010
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mimedx Group, Inc.
Location	Marietta, GA, US
Contact	LOUISE FOCHT
510(k) history	5 submissions · 2 cleared · 2010-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100905/> Data sourced from FDA 510(k) public records (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. - Generated June 19, 2026