

K101805 HYDROFIX VASO SHIELDApr 8, 2011
284 days to decisionK101805 · Product code: **OMR** · CardiovascularSource: <https://www.510kdatabase.net/k101805/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Vessel Guard Or Cover (OMR)
Date received	Jun 28, 2010
Decision date	Apr 8, 2011
Days to decision	284 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101805/> 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