

**K043371 BIOMERIX VASCULAR OCCLUSION DEVICE AND
LOADER**Feb 3, 2005
57 days to decisionK043371 · Product code: **KRD** · Cardiovascular
Source: <https://www.510kdatabase.net/k043371/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Dec 8, 2004
Decision date	Feb 3, 2005
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomerix Corporation
Location	Rockville, MD, US
Contact	CHRISTINA L KICHULA
510(k) history	6 submissions · 6 cleared · 2005-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043371/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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