FDA 510(k) Premarket Notification

K043371 BIOMERIX VASCULAR OCCLUSION DEVICE AND LOADER

CLEARED

Feb 3, 2005
57 days to decision

K043371 · 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