

**K203025 LOBO Vascular Occlusion System (model LOBO-5)**Nov 5, 2020  
34 days to decisionK203025 · Product code: **KRD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k203025/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Oct 2, 2020
Decision date	Nov 5, 2020
Days to decision	34 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Okami Medical</b>
Location	Aliso Viejo, CA, US
Contact	Jill Delsman
510(k) history	3 submissions · 3 cleared · 2019-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203025/> 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 May 27, 2026