

**K213385 GEM**Jul 1, 2022  
261 days to decisionK213385 · Product code: **KRD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k213385/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Oct 13, 2021
Decision date	Jul 1, 2022
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Obsidio, Inc.</b>
Location	Columbia, SC, US
Contact	Ehsan Jabbarzadeh
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Boston Scientific Corporation</b>
Contact	Heidi Shearer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213385/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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