

**K130307 ONCOZENE MICROSPHERES 40UM, 2ML, ONCOZENE MICROSPHERES 75UM, 2ML, ONCOZENE MICROSPHERES 100UM, 2ML, ONCOZENE MICROSPHERE**Mar 4, 2013  
25 days to decisionK130307 · Product code: **KRD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k130307/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Feb 7, 2013
Decision date	Mar 4, 2013
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Celonova Biosciences, Inc.</b>
Location	Newnan, GA, US
Contact	NICOLE BARBER
510(k) history	5 submissions · 5 cleared · 2008-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130307/>; 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 June 6, 2026