

**K141209 EMBOZENE COLOR-ADVANCED MICROSPHERES,
EMBOZENE OPAQUE (NON-COLORED) MICROSPHERES,
ONCOZENE MICROSPHERES**Aug 7, 2014
90 days to decisionK141209 · Product code: **KRD** · Cardiovascular
Source: <https://www.510kdatabase.net/k141209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	May 9, 2014
Decision date	Aug 7, 2014
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141209/> Data sourced from FDA 510(k) public records (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. - Generated June 6, 2026