

K132675 EMBOZENE MICROSPHERESOct 3, 2013
36 days to decisionK132675 · Product code: **KRD** · Cardiovascular
Source: <https://www.510kdatabase.net/k132675/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Aug 28, 2013
Decision date	Oct 3, 2013
Days to decision	36 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/k132675/> 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