

**K133447 EMBOZENE COLOR-ADVANCED MICROSPHERES,
EMBOZENE OPAQUE (NON-COLORED) MICROSPHERES**Feb 24, 2014
104 days to decisionK133447 · Product code: **NAJ** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k133447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agents, Embolic, For Treatment Of Uterine Fibroids (NAJ)
Date received	Nov 12, 2013
Decision date	Feb 24, 2014
Days to decision	104 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

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