

**K173871 CalliSpheres Embolic Microspheres, 8Spheres
Embolic Microspheres**Sep 17, 2018
271 days to decisionK173871 · Product code: **NAJ** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k173871/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agents, Embolic, For Treatment Of Uterine Fibroids (NAJ)
Date received	Dec 20, 2017
Decision date	Sep 17, 2018
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Hengrui Callisyn Biomedical Co., Ltd.
Location	Suzhou, CN
Contact	Xiao Chen
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173871/>. 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 22, 2026