

K250971 Embosphere MicrospheresMay 16, 2025
46 days to decisionK250971 · Product code: **KRD** · CardiovascularSource: <https://www.510kdatabase.net/k250971/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Mar 31, 2025
Decision date	May 16, 2025
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biosphere Medical, S.A.
Location	Roissy-En-France, FR
Contact	Rosene Amosse
510(k) history	10 submissions · 9 cleared · 2015-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250971/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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