

K151187 QuadraSphere MicrospheresJul 27, 2015
84 days to decisionK151187 · Product code: **KRD** · Neurology
Source: <https://www.510kdatabase.net/k151187/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	May 4, 2015
Decision date	Jul 27, 2015
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151187/> 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 May 27, 2026