

K181300 Embosphere MicrospheresJul 16, 2018
60 days to decisionK181300 · Product code: **KRD** · Neurology
Source: <https://www.510kdatabase.net/k181300/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	May 17, 2018
Decision date	Jul 16, 2018
Days to decision	60 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

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