

K153102 QuadraSphere MicrospheresNov 23, 2015
28 days to decisionK153102 · Product code: **KRD** · Neurology
Source: <https://www.510kdatabase.net/k153102/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Oct 26, 2015
Decision date	Nov 23, 2015
Days to decision	28 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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