

K183120 EmboCube Embolization GelatinAug 6, 2019
270 days to decisionK183120 · Product code: **KRD** · Cardiovascular
Source: <https://www.510kdatabase.net/k183120/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Nov 9, 2018
Decision date	Aug 6, 2019
Days to decision	270 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/k183120/> 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