

K181021 EmboCube Embolization GelatinSep 27, 2018
163 days to decisionK181021 · Product code: **KRD** · Cardiovascular
Source: <https://www.510kdatabase.net/k181021/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Vascular, For Promoting Embolization (KRD) |
| Date received | Apr 17, 2018 |
| Decision date | Sep 27, 2018 |
| Days to decision | 163 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/k181021/> 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