

K183578 Torpedo Gelatin FoamJun 18, 2019
179 days to decisionK183578 · Product code: **KRD** · Cardiovascular
Source: <https://www.510kdatabase.net/k183578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Dec 21, 2018
Decision date	Jun 18, 2019
Days to decision	179 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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