FDA 510(k) Premarket Notification

K192480 Torpedo Gelatin Foam

CLEARED

Nov 21, 2019
72 days to decision

K192480 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k192480/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Sep 10, 2019
Decision date	Nov 21, 2019
Days to decision	72 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.net
Device record: https://www.510kdatabase.net/k192480/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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