FDA 510(k) Premarket Notification

CLEARED

K181021 EmboCube Embolization Gelatin

Sep 27, 2018
163 days to decision

K181021 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k181021/

SUBMISSION DETAILS

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