FDA 510(k) Premarket Notification

K183120 EmboCube Embolization Gelatin

CLEARED

Aug 6, 2019
270 days to decision

K183120 · 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