FDA 510(k) Premarket Notification

K213385 GEM

CLEARED

Jul 1, 2022
261 days to decision

K213385 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k213385/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Oct 13, 2021
Decision date	Jul 1, 2022
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Obsidio, Inc.**
Location	Columbia, SC, US
Contact	Ehsan Jabbarzadeh
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Boston Scientific Corporation**
Contact	Heidi Shearer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov