FDA 510(k) Premarket Notification

CLEARED

K182390 IMPEDE-FX Embolization Plug

May 23, 2019
261 days to decision

K182390 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k182390/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Sep 4, 2018
Decision date	May 23, 2019
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shape Memory Medical**
Location	Santa Clara, CA, US
Contact	Meghan Reu
510(k) history	2 submissions · 2 cleared · 2018-2019