

K182390 IMPEDE-FX Embolization PlugMay 23, 2019
261 days to decisionK182390 · Product code: **KRD** · CardiovascularSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182390/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026