

K181051 IMPEDE Embolization Plug, 5mm, IMPEDE Embolization Plug, 7mm, IMPEDE Embolization Plug, 10mmJun 22, 2018
63 days to decisionK181051 · Product code: **KRD** · Cardiovascular
Source: <https://www.510kdatabase.net/k181051/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Apr 20, 2018
Decision date	Jun 22, 2018
Days to decision	63 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

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