

K200083 EMBA Hourglass Peripheral Embolization Device (PED)Feb 14, 2020
30 days to decisionK200083 · Product code: **KRD** · Cardiovascular
Source: <https://www.510kdatabase.net/k200083/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Jan 15, 2020
Decision date	Feb 14, 2020
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Embolic Acceleration, LLC
Location	Miami, FL, US
Contact	Veronica McDougall
510(k) history	1 submissions · 1 cleared · 2020-2020

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