

K171845 EMBA Hourglass Peripheral Embolization DeviceAug 18, 2017
59 days to decisionK171845 · Product code: **KRD** · CardiovascularSource: <https://www.510kdatabase.net/k171845/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Jun 20, 2017
Decision date	Aug 18, 2017
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Emba Medical Limited
Location	Miami, FL, US
Contact	Veronica Reott
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171845/> 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 1, 2026