FDA 510(k) Premarket Notification

K160219 Hilal Embolization MicroCoils

CLEARED

Aug 3, 2016
187 days to decision

K160219 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k160219/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Jan 29, 2016
Decision date	Aug 3, 2016
Days to decision	187 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cook Incorporated**
Location	Bloomington, IN, US
Contact	David Lehr
510(k) history	175 submissions · 153 cleared · 2006-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k160219/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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