FDA 510(k) Premarket Notification

K151676 Retracta Detachable Embolization Coil

CLEARED

Jul 22, 2015
30 days to decision

K151676 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k151676/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Jun 22, 2015
Decision date	Jul 22, 2015
Days to decision	30 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