FDA 510(k) Premarket Notification

K183374 GrayDuck Stent

CLEARED

Feb 26, 2019
82 days to decision

K183374 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k183374/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Dec 6, 2018
Decision date	Feb 26, 2019
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Poll Medical, LLC**
Location	Beaverton, OR, US
Contact	Adrian Polliack
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Allegiance Regulatory Consulting, LLC**
Contact	Alyssa Thomas

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov