FDA 510(k) Premarket Notification

K190369 M-Y Sheath

CLEARED

Apr 17, 2019
61 days to decision

K190369 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k190369/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Feb 15, 2019
Decision date	Apr 17, 2019
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ram Medical Innovations, Inc.**
Location	Springfield, OH, US
Contact	Mubin Syed
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Lamamed Solutions, Inc.**
Contact	Lloyd H Griese

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