FDA 510(k) Premarket Notification

K190619 Aspiron(TM) Aspiration Catheter

CLEARED

Apr 29, 2019
49 days to decision

K190619 · Product code: **QEZ** · Cardiovascular
Source: https://www.510kdatabase.net/k190619/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Mar 11, 2019
Decision date	Apr 29, 2019
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Meril Life Sciences Private Limited**
Location	Baltimore, MD, US
Contact	Utpal Thakor
510(k) history	4 submissions · 4 cleared · 2013-2019

REGULATORY CONSULTANT

Consulting firm	**CardioMed Device Consultants, LLC**
Contact	H. Semih Oktay

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