

K190619 Aspiron(TM) Aspiration CatheterApr 29, 2019
49 days to decisionK190619 · 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](https://accessdata.fda.gov)

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