FDA 510(k) Premarket Notification

K173430 SeQure® NF and SeQure® Microcatheters

CLEARED

Jan 26, 2018
85 days to decision

K173430 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k173430/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Nov 2, 2017
Decision date	Jan 26, 2018
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Accurate Medical Therapeutics, Ltd.**
Location	Tel-Aviv, IL
Contact	Eran Miller
510(k) history	3 submissions · 3 cleared · 2018-2020

REGULATORY CONSULTANT

Consulting firm	**Orly Maor**
Contact	Orly Maor

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