

K203487 Drakon and Sequire MicrocathetersDec 11, 2020
14 days to decisionK203487 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k203487/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Nov 27, 2020
Decision date	Dec 11, 2020
Days to decision	14 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	Osnat Harbater
510(k) history	3 submissions · 3 cleared · 2018-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203487/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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