

K202797 Drakon and Seure MicrocathetersOct 23, 2020
30 days to decisionK202797 · Product code: **DQO** · CardiovascularSource: <https://www.510kdatabase.net/k202797/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Sep 23, 2020
Decision date	Oct 23, 2020
Days to decision	30 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/k202797/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026