

K161262 Super Distal Access (SDA)Sep 19, 2016
137 days to decisionK161262 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k161262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	May 5, 2016
Decision date	Sep 19, 2016
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Inneuroco, Inc.
Location	Sunrise, FL, US
Contact	Marc Litzenberg
510(k) history	9 submissions · 9 cleared · 2016-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161262/> 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 May 26, 2026