

K171672 065 Zenith, 074 ZenithOct 19, 2017
135 days to decisionK171672 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k171672/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 6, 2017
Decision date	Oct 19, 2017
Days to decision	135 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

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