

K181354 074 Zenith Flex SystemOct 25, 2018
156 days to decisionK181354 · Product code: **NRY** · Neurology
Source: <https://www.510kdatabase.net/k181354/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Thrombus Retriever (NRY)
Date received	May 22, 2018
Decision date	Oct 25, 2018
Days to decision	156 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/k181354/> 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