

**K231629 091 Balloon Guide Catheter**Oct 31, 2023  
148 days to decisionK231629 · Product code: **DQY** · Neurology  
Source: <https://www.510kdatabase.net/k231629/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 5, 2023
Decision date	Oct 31, 2023
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Eosolutions, Corp.</b>
Location	Pembroke Pines, FL, US
Contact	Marc Litzenberg
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Inneuroco, Inc.</b>
Contact	Garry Koroshec

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231629/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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