

**K233394 Gem Flow Now (GEM2770-FN)**Jan 28, 2024  
117 days to decisionK233394 · Product code: IYN · Cardiovascular  
Source: <https://www.510kdatabase.net/k233394/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 3, 2023
Decision date	Jan 28, 2024
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synovis Micro Companies Alliance</b>
Location	Birmingham, AL, US
Contact	Julie Carlston
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233394/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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