

**K232328 Insignis™ Syringe Infusion System**Mar 1, 2024  
211 days to decisionK232328 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k232328/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Aug 3, 2023
Decision date	Mar 1, 2024
Days to decision	211 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innovative Health Sciences, LLC</b>
Location	Chester, NY, US
Contact	Phil Daetwyler
510(k) history	2 submissions · 2 cleared · 2021-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232328/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026