

**K150921 Orbit Infusion Set**Apr 12, 2016  
372 days to decisionK150921 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k150921/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Apr 6, 2015
Decision date	Apr 12, 2016
Days to decision	372 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ypsomed AG</b>
Location	Burgdorf, CH
Contact	STEPHAN AFFOLTER
510(k) history	12 submissions · 12 cleared · 2010-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150921/> 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 26, 2026