

**K243901 SmartPilot YpsoMate NS-A2.25**Aug 28, 2025  
252 days to decisionK243901 · Product code: **QOG** · General Hospital  
Source: <https://www.510kdatabase.net/k243901/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injection Data Capture Device (QOG)
Date received	Dec 19, 2024
Decision date	Aug 28, 2025
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ypsomed AG</b>
Location	Burgdorf, CH
Contact	Johannes Schmid
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/k243901/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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