

**K240315 INNOVANCE Anti-Xa (OPPU05)**Oct 10, 2024  
251 days to decisionK240315 · Product code: **QLU** · Hematology  
Source: <https://www.510kdatabase.net/k240315/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-factor Xa Activity Test System, Apixaban (QLU)
Date received	Feb 2, 2024
Decision date	Oct 10, 2024
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	INNOVANCE Apixaban Standards (OPPW05); INNOVANCE Apixaban Controls (OPPS05)

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics Products GmbH</b>
Location	Marburg, DE
Contact	Anja Wilhelm
510(k) history	19 submissions · 18 cleared · 2016-2024

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