

**K242128 Forsvall biopsy needle system for prostate biopsy  
(Forsvall biopsy gun and Forsvall biopsy needle)**Feb 27, 2025  
223 days to decisionK242128 · Product code: **KNW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k242128/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jul 19, 2024
Decision date	Feb 27, 2025
Days to decision	223 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xaga Surgical</b>
Location	Helsingborg, SE
Contact	Anders Grim
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242128/> 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 13, 2026