

**K201650 VMCore Biopsy Needle**Jan 15, 2021  
211 days to decisionK201650 · Product code: **KNW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k201650/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jun 18, 2020
Decision date	Jan 15, 2021
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Uro-1, Inc.</b>
Location	Winston Salem, NC, US
Contact	Thomas Lawson
510(k) history	3 submissions · 3 cleared · 2018-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201650/> 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