

**K220611 SUREcore Plus Biopsy Instrument**Dec 2, 2022  
274 days to decisionK220611 · Product code: **KNW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220611/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Mar 3, 2022
Decision date	Dec 2, 2022
Days to decision	274 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/k220611/> 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