

**K230646 SUREcore Prime Biopsy Instrument**Nov 29, 2023  
266 days to decisionK230646 · Product code: **KNW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k230646/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Mar 8, 2023
Decision date	Nov 29, 2023
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Uro-1 Medical, Inc.</b>
Location	Greensboro, NC, US
Contact	Thomas Lawson, PhD
510(k) history	1 submissions · 1 cleared · 2023-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230646/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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