

**K222865 M Biopsy /SureCore Automatic Disposable Biopsy Needle, M Biopsy /SureCore Semi-Automatic Disposable Biopsy Needle, M Biopsy /SureAim Coaxial Biopsy Needle**Apr 3, 2023  
193 days to decisionK222865 · Product code: **KNW** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k222865/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Sep 22, 2022
Decision date	Apr 3, 2023
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Canyon Medical, Inc.</b>
Location	Nanjing, CN
Contact	Huiqi Jiang
510(k) history	5 submissions · 5 cleared · 2023-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222865/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026