

**K233031 M-Biopsy /SureCore Automatic Disposable Biopsy Needle, M-Biopsy /SureCore Semi-automatic Disposable Biopsy Needle, M-Biopsy /SureAim Coaxial Biopsy Needle**Jan 17, 2024  
114 days to decisionK233031 · Product code: **KNW** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k233031/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Sep 25, 2023
Decision date	Jan 17, 2024
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233031/> 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 14, 2026