

K243296 Disposable Biopsy NeedleJul 11, 2025
266 days to decisionK243296 · Product code: **KNW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k243296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Oct 18, 2024
Decision date	Jul 11, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Carbon (Shenzhen) Medical Device Co., Ltd.
Location	Shenzhen, CN
Contact	Min Ye
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Linnwell International Certification Consulting Co., Ltd.
Contact	Jishan Jin

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243296/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026