

K243095 Mammotome AutoCore™ Single Insertion Core Biopsy SystemOct 29, 2024
29 days to decisionK243095 · Product code: **KNW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k243095/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Sep 30, 2024
Decision date	Oct 29, 2024
Days to decision	29 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Devicor Medical Products, Inc.
Location	Cincinnati, OH, US
Contact	Edenborg Jamie
510(k) history	16 submissions · 16 cleared · 2012-2026

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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/k243095/> 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 14, 2026