CLEARED

K260365 Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Control Module

Mar 4, 2026
28 days to decision

K260365 · Product code: **KNW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k260365/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Feb 4, 2026
Decision date	Mar 4, 2026
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Disposable Probe, 8 gauge; Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Disposable Targeting Set, 8 gauge; Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Foot Switch; Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Reusable Tray; Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Battery Char

APPLICANT

Company	**Devicor Medical Products, Inc.**
Location	Cincinnati, OH, US
Contact	Jamie Edenborg
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