

**K202012 Mammotome Revolve Dual Vacuum Assisted Biopsy (VAB) System**Aug 18, 2020  
28 days to decisionK202012 · Product code: **KNW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k202012/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jul 21, 2020
Decision date	Aug 18, 2020
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Devicor Medical Products, Inc.</b>
Location	Cincinnati, OH, US
Contact	Gwendolyn P. Payne
510(k) history	16 submissions · 16 cleared · 2012-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
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)

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