

**K153709 Mammotome elite Biopsy System-13G Probe,  
Mammotome elite Biopsy System-10G Probe, Mammotome elite  
Biopsy System-Holster, Mammotome elite Biopsy System-13G  
Introducer Stylet, Mammotome elite Biopsy System-10G  
Introducer Stylet**Aug 8, 2016  
229 days to decisionK153709 · Product code: **KNW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k153709/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Dec 23, 2015
Decision date	Aug 8, 2016
Days to decision	229 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153709/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 2, 2026