

**K142125 New Medax Biopsy Systems**Dec 22, 2015  
505 days to decisionK142125 · Product code: **KNW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k142125/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Aug 4, 2014
Decision date	Dec 22, 2015
Days to decision	505 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Medax Srl Unipersonale</b>
Location	Poggio Rusco, IT
Contact	Stefano Cavalieri
510(k) history	5 submissions · 5 cleared · 2015-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k142125/> 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 28, 2026