

**K130616 MANUAL-BONE-MARROW-BIOPSY-NEEDLES, SEMI-AUTOMATIC-BIOPSY-NEEDLES, AUTOMATIC-BIOPSY-NEEDLES**Feb 7, 2014  
337 days to decisionK130616 · Product code: **KNW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k130616/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Mar 7, 2013
Decision date	Feb 7, 2014
Days to decision	337 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biopsybell S.R.L.</b>
Location	Verona, NJ, US
Contact	WILLER GHELFI
510(k) history	4 submissions · 4 cleared · 2014-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130616/> 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 May 26, 2026