

**K131140 OMNYX IDP FOR HER2 MANUAL APPLICATION**Apr 1, 2014  
344 days to decisionK131140 · Product code: **OEO** · Pathology  
Source: <https://www.510kdatabase.net/k131140/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Digital Image Manual Interpretation Microscope (OEO)
Date received	Apr 22, 2013
Decision date	Apr 1, 2014
Days to decision	344 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omnyx, LLC</b>
Location	Marlborough, MA, US
Contact	GAIL E RADCLIFFE
510(k) history	1 submissions · 1 cleared · 2014-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131140/> 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 13, 2026