

**K161467 HydraGuard 10 UltraFilter**Dec 22, 2016  
209 days to decisionK161467 · Product code: **NHV** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k161467/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Water Purification, General Medical Use (NHV)
Date received	May 27, 2016
Decision date	Dec 22, 2016
Days to decision	209 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Nephros, Inc.</b>
Location	New York, NY, US
Contact	JAMES SUMMERTON
510(k) history	8 submissions · 8 cleared · 2005-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161467/> 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 1, 2026