

**K153084 Nephros S100**Apr 8, 2016  
165 days to decisionK153084 · Product code: **NHV** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k153084/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                    |
| Submission type       | Traditional   |
| Device classification | System, Water Purification, General Medical Use (NHV) |
| Date received         | Oct 26, 2015  |
| Decision date         | Apr 8, 2016   |
| Days to decision      | 165 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**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/k153084/> 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