

**K250800 UroNav 4**Jun 5, 2025  
83 days to decisionK250800 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k250800/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 14, 2025
Decision date	Jun 5, 2025
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Philips DS North America, LLC</b>
Location	Gainesville, FL, US
Contact	Sagar Pimpalwar
510(k) history	1 submissions · 1 cleared · 2025-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250800/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026