FDA 510(k) Premarket Notification

K250800 UroNav 4

CLEARED

Jun 5, 2025
83 days to decision

K250800 · 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	**Philips DS North America, LLC**
Location	Gainesville, FL, US
Contact	Sagar Pimpalwar
510(k) history	1 submissions · 1 cleared · 2025-2025