

K250664 Navigo Workstation 2.3 (FPRMC00039)Aug 7, 2025
155 days to decisionK250664 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k250664/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 5, 2025
Decision date	Aug 7, 2025
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	UC-CARE , Ltd.
Location	Washington, DC, US
Contact	Hadas Sheynise
510(k) history	5 submissions · 5 cleared · 2009-2025

REGULATORY CONSULTANT

Consulting firm	Gsap
Contact	Avital Levertov

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250664/> 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