

**K222080 Garion Image-Intensified Fluoroscopic X-Ray System,
Mobile**Oct 6, 2022
83 days to decisionK222080 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k222080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jul 15, 2022
Decision date	Oct 6, 2022
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sg Healthcare Co, Ltd.
Location	Hanam-Si Gyeonggi-Do, KR
Contact	Byung Ju Kang
510(k) history	3 submissions · 3 cleared · 2015-2023

REGULATORY CONSULTANT

Consulting firm	Kamm & Associates
Contact	Daniel Kamm

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222080/> 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 26, 2026