

K252229 BELLIGER ACEApr 2, 2026
260 days to decisionK252229 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k252229/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jul 16, 2025
Decision date	Apr 2, 2026
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genoray Co., Ltd.
Location	Flintville, TN, US
Contact	Dongwon Kang
510(k) history	24 submissions · 24 cleared · 2007-2026

REGULATORY CONSULTANT

Consulting firm	Genoray America, Inc.
Contact	Simon Jo

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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