

K140041 ZEN-7000,SYSTEM,FLUROSCOPIC X-RAY SYSTEMNov 28, 2014
324 days to decisionK140041 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k140041/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jan 8, 2014
Decision date	Nov 28, 2014
Days to decision	324 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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