

**K091918 ZEN-2090 PRO, FLUOROSCOPIC X-RAY SYSTEM,  
MODEL ZEN-2090 PRO**Oct 7, 2009  
99 days to decisionK091918 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k091918/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jun 30, 2009
Decision date	Oct 7, 2009
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genoray Co., Ltd.</b>
Location	Flintville, TN, US
Contact	SHIN KUK YOO
510(k) history	24 submissions · 24 cleared · 2007-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091918/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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