

**K181943 OSCAR (OSCAR Prime, OSCAR Classic)**Aug 17, 2018  
28 days to decisionK181943 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k181943/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jul 20, 2018
Decision date	Aug 17, 2018
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genoray Co., Ltd.</b>
Location	Flintville, TN, US
Contact	Jeff Hwang
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/k181943/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026