

**K230787 Oscar 15 & Oscar 15i**Jul 20, 2023  
120 days to decisionK230787 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k230787/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Mar 22, 2023
Decision date	Jul 20, 2023
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Genoray America, Inc.</b>
Contact	Kaitlynn Min

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230787/> 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 14, 2026