

K172180 OSCAR 15Feb 9, 2018
205 days to decisionK172180 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k172180/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jul 19, 2017
Decision date	Feb 9, 2018
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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