

K172700 OEC OneNov 9, 2017
63 days to decisionK172700 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k172700/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 7, 2017
Decision date	Nov 9, 2017
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Hualun Medical Systems Co. , Ltd.
Location	Beijing, CN
Contact	Lifeng Wang
510(k) history	12 submissions · 12 cleared · 2015-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172700/> 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 26, 2026