

K160065 GEMSS Medical System Surgical Mobile Fluoroscopic X-ray SystemMay 20, 2016
128 days to decisionK160065 · Product code: **OXO** · Radiology
Source: <https://www.510kdatabase.net/k160065/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image-intensified Fluoroscopic X-ray System, Mobile (OXO)
Date received	Jan 13, 2016
Decision date	May 20, 2016
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gemss Medical Systems Co., Ltd.
Location	Houston, TX, US
Contact	Sang Woo Lee
510(k) history	4 submissions · 4 cleared · 2014-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160065/> 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 16, 2026