

**K163140 SPINEL 12HD Interventional Fluoroscopic Mobile X-ray System**May 26, 2017  
198 days to decisionK163140 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k163140/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Nov 9, 2016
Decision date	May 26, 2017
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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