

**K161955 5D Viewer**Aug 10, 2016  
23 days to decisionK161955 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k161955/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 18, 2016
Decision date	Aug 10, 2016
Days to decision	23 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Samsung Medison Co., Ltd.</b>
Location	Seoul, KR
Contact	Kyeong-Mi Park
Website	<a href="http://www.medison.com/">http://www.medison.com/</a>
510(k) history	72 submissions · 72 cleared · 2011-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161955/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026