

**K092581 MITS DICOM GATEWAY AND IMAGE MANAGER**Oct 30, 2009  
70 days to decisionK092581 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k092581/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 21, 2009
Decision date	Oct 30, 2009
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mitsmed Medical Instrument Technology Co., Ltd.</b>
Location	Hsin Chu City, TW
Contact	Ke-Min Jen
510(k) history	1 submissions · 1 cleared · 2009-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092581/> 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 17, 2026