

**K061447 5M MONOCHROME DIGITAL MAMMOGRAPHY LCD  
MONITOR MDL2116A (ME551I2)**Jul 21, 2006  
57 days to decisionK061447 · Product code: LLZ · Radiology  
Source: <https://www.510kdatabase.net/k061447/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 25, 2006
Decision date	Jul 21, 2006
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Totoku Electric Co., Ltd.</b>
Location	Mie-Ken, JP
Contact	MIKIO HASEGAWA
510(k) history	40 submissions · 40 cleared · 2001-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061447/>; 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