

**K133686 21.3 INCH (54 CM) INCH MONOCHROME DIGITAL MAMMOGRAPHY LCD MONITOR MS35i2 (ML21035)**Jan 6, 2014  
35 days to decisionK133686 · Product code: LLZ · Radiology  
Source: <https://www.510kdatabase.net/k133686/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 2, 2013
Decision date	Jan 6, 2014
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jvckenwood Corporation</b>
Location	Nagano-Ken, JP
Contact	TSUKASA TASHIRO
Website	<a href="http://www.jvckenwood.com/">http://www.jvckenwood.com/</a>
510(k) history	22 submissions · 22 cleared · 2013-2024

Jvckenwood Corporation is a Japanese electronics manufacturer with a manufacturing facility in Nagano-Ken, Japan. The company specializes in medical display technology for diagnostic imaging applications. Jvckenwood has received FDA 510(k) clearances from total submissions since 2013. The company focuses exclusively on Radiology devices, with no denied submissions on record. The latest clearance was in 2024, confirming active regulatory engagement. The company's cleared portfolio consists primarily of color and monochrome LCD monitors for medical imaging. These include mo...

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