

**K200161 3MP Monochrome Digital Mammography LCD Monitor  
MS-S300**Feb 21, 2020  
30 days to decisionK200161 · Product code: **PGY** · Radiology  
Source: <https://www.510kdatabase.net/k200161/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Jan 22, 2020
Decision date	Feb 21, 2020
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jvckenwood Corporation</b>
Location	Nagano-Ken, JP
Contact	Hideki Tengeiji
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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