

**K210345 2MP Monochrome LCD Monitor MS-S200**Apr 23, 2021  
77 days to decisionK210345 · Product code: **PGY** · Radiology  
Source: <https://www.510kdatabase.net/k210345/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Feb 5, 2021
Decision date	Apr 23, 2021
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	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...