

K160326 5MP Monochrome LCD Monitor MS55i2, 5MP Color LCD Monitor CCL550i2 (CL21550)Feb 23, 2016
18 days to decisionK160326 · Product code: **PGY** · Radiology
Source: <https://www.510kdatabase.net/k160326/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Feb 5, 2016
Decision date	Feb 23, 2016
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Jvckenwood Corporation
Location	Nagano-Ken, JP
Contact	Tsukasa Tashiro
Website	http://www.jvckenwood.com/
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...