

K222864 8MP Color LCD Monitor CL-R813Dec 21, 2022
90 days to decisionK222864 · Product code: **PGY** · Radiology
Source: <https://www.510kdatabase.net/k222864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Sep 22, 2022
Decision date	Dec 21, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jvckenwood Corporation
Location	Nagano-Ken, JP
Contact	Hideki Tengeiji
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...