

**K161895 2MP Color LCD Monitor CCL214 (CL21214)**Sep 8, 2016  
59 days to decisionK161895 · Product code: **PGY** · Radiology  
Source: <https://www.510kdatabase.net/k161895/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Display, Diagnostic Radiology (PGY) |
| Date received         | Jul 11, 2016                        |
| Decision date         | Sep 8, 2016                         |
| Days to decision      | 59 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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