

K161057 Diagnostic Imaging Color LCD MonitorMay 13, 2016
29 days to decisionK161057 · Product code: **PGY** · Radiology
Source: <https://www.510kdatabase.net/k161057/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Display, Diagnostic Radiology (PGY) |
| Date received | Apr 14, 2016 |
| Decision date | May 13, 2016 |
| Days to decision | 29 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Nec Display Solutions , Ltd. |
| Location | Ashigarakami-Gun, Kanagawa, JP |
| Contact | SATORU KOTANI |
| 510(k) history | 15 submissions · 15 cleared · 2006-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161057/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026