

K171812 Nio Color 2MP (MDNC-2123)Jul 19, 2017
30 days to decisionK171812 · Product code: **PGY** · Radiology
Source: <https://www.510kdatabase.net/k171812/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Display, Diagnostic Radiology (PGY) |
| Date received | Jun 19, 2017 |
| Decision date | Jul 19, 2017 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Barco N.V. |
| Location | La Jolla, CA, US |
| Contact | Helena Soenen |
| Website | http://www.barco.com |
| 510(k) history | 60 submissions · 60 cleared · 1998-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171812/> 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