

K243893 Second Opinion® PediatricMay 5, 2025
138 days to decisionK243893 · Product code: **MYN** · Radiology
Source: <https://www.510kdatabase.net/k243893/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Analyzer, Medical Image (MYN) |
| Date received | Dec 18, 2024 |
| Decision date | May 5, 2025 |
| Days to decision | 138 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Pearl, Inc. |
| Location | Beverly Hills, CA, US |
| Contact | Ashley Brown |
| 510(k) history | 8 submissions · 8 cleared · 2022-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243893/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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