

K211720 Planned Clarity 2D, Planned Clarify SJul 18, 2022
409 days to decisionK211720 · Product code: **MUE** · Radiology
Source: <https://www.510kdatabase.net/k211720/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Full Field Digital, System, X-ray, Mammographic (MUE) |
| Date received | Jun 4, 2021 |
| Decision date | Jul 18, 2022 |
| Days to decision | 409 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Planned OY |
| Location | Helsinki, FI |
| Contact | Niina Vuorikallas |
| 510(k) history | 20 submissions · 20 cleared · 1992-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211720/> 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 14, 2026