

K241006 Natural CyclesJul 11, 2024
90 days to decisionK241006 · Product code: **PYT** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k241006/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Fertility Diagnostic, Contraceptive, Software Application (PYT) |
| Date received | Apr 12, 2024 |
| Decision date | Jul 11, 2024 |
| Days to decision | 90 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | Yes - Predetermined Change Control Plan (AI/SaMD) |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Natural Cycles Nordic AB |
| Location | Stockholm, SE |
| Contact | Megan Callanan |
| 510(k) history | 5 submissions · 4 cleared · 2018-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241006/> 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 13, 2026