

K202897 Natural CyclesJun 24, 2021
268 days to decisionK202897 · Product code: **PYT** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k202897/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Fertility Diagnostic, Contraceptive, Software Application (PYT)
Date received	Sep 29, 2020
Decision date	Jun 24, 2021
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Heyer Regulatory Solutions, LLC
Contact	Sheila Hemeon-Heyer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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