

**K222969 FERTI-LILY Conception Cup**Jun 23, 2023  
269 days to decisionK222969 · Product code: **HDR** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k222969/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cap, Cervical (HDR)
Date received	Sep 27, 2022
Decision date	Jun 23, 2023
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rosesta Medical BV</b>
Location	Amsterdam, NL
Contact	Stal Robert
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>CRA Solutions, Inc.</b>
Contact	Jill Matzat

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222969/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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