FDA 510(k) Premarket Notification

K222969 FERTI-LILY Conception Cup

CLEARED

Jun 23, 2023
269 days to decision

K222969 · Product code: **HDR** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k222969/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**CRA Solutions, Inc.**
Contact	Jill Matzat

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