

K241009 PeriCALM Patterns 3.0Jan 10, 2025
273 days to decisionK241009 · Product code: **HGM** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k241009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Apr 12, 2024
Decision date	Jan 10, 2025
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Perigen, Inc.
Location	Rishon Letziyon, IL
Contact	Alva Candace
Website	https://perigen.com
510(k) history	1 submissions · 1 cleared · 2025-2025

Perigen, Inc. develops perinatal software solutions designed to support maternal and fetal safety during labor and delivery. The company creates advanced technology platforms that help clinical teams identify potential risks early and improve patient outcomes. Perigen operates with a manufacturing facility in Rishon Letziyon, IL. Perigen has received FDA 510(k) clearance from total submission. The company specializes exclusively in Obstetrics & Gynecology devices. First cleared in 2025, Perigen remains actively engaged in regulatory submissions and product development. Th...