

**K191401 PregSense**Mar 27, 2020  
308 days to decisionK191401 · Product code: **LQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k191401/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Home Uterine Activity Monitor (LQK)
Date received	May 24, 2019
Decision date	Mar 27, 2020
Days to decision	308 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nuvo- Group , Ltd.</b>
Location	Tel Aviv, IL
Contact	Adar Shani
510(k) history	3 submissions · 3 cleared · 2020-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191401/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026