

**K221046 Invu by Nuvo**May 6, 2022  
28 days to decisionK221046 · Product code: **LQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k221046/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Home Uterine Activity Monitor (LQK)
Date received	Apr 8, 2022
Decision date	May 6, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Janice Hogan

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

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