

K210025 INVU by NuvoMay 28, 2021
144 days to decisionK210025 · Product code: **LQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k210025/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Home Uterine Activity Monitor (LQK)
Date received	Jan 4, 2021
Decision date	May 28, 2021
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
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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