FDA 510(k) Premarket Notification

K221046 Invu by Nuvo

CLEARED

May 6, 2022
28 days to decision

K221046 · Product code: **LQK** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k221046/

SUBMISSION DETAILS

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

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