May 6, 2022

Nuvo- Group Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philladelphia, PA 19103

Re: K221046
Trade/Device Name: INVU by Nuvo™
Regulation Number: 21 CFR§ 884.2730
Regulation Name: Home uterine activity monitor
Regulatory Class: II
Product Code: LQK
Dated: April 8, 2022
Received: April 8, 2022

Dear Janice Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221046

Device Name
INVU by Nuvo™

Indications for Use *(Describe)*
INVU by Nuvo™ is a maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR), maternal heart rate (MHR) and Uterine Activity (UA).

The INVU Sensor Band™ acquires the fetal heart electrocardiogram and maternal heart electrocardiogram signals from abdominal surface electrodes and the fetal phonocardiogram and the maternal phonocardiogram signals from surface acoustic sensors. The FHR, MHR and UA tracings are derived from these signals and presented.

INVU by Nuvo™ is indicated for use by pregnant women who are in their 32nd week of gestation (or later), with a singleton pregnancy.

The INVU by Nuvo™ maternal-fetal monitor is intended for use by healthcare professionals in health care facilities and by the patient in the patient's home, on the order of a physician.

The INVU by Nuvo™ is indicated for antepartum fetal surveillance (i.e. non-stress testing).

This system does not prevent the onset of preterm labor nor will it prevent the occurrence of preterm birth.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Special 510(k) SUMMARY – K221046

Nuvo Group Ltd.'s INVU by Nuvo™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Nuvo-Group Ltd.
Yigal Alon 94 St., Alon Tower 1
Tel Aviv, Israel 6789155
Phone: +972-54 3063996
Contact Person: Chen Rubinstein

Date Prepared: May 4, 2022

Device Information

Trade Name	INVU by Nuvo™
Common Name	Home Uterine Activity Monitor
Regulation Number	21 CFR 884.2730
Regulation Name	Home uterine activity monitor
Product Code	LQK (Home Uterine Activity Monitor)
Classification Panel	Obstetrics/Gynecology
Regulatory Class	II

Predicate Device

K210025 INVU by Nuvo™

The predicate device has not been subject to a design-related recall.

Device Description

INVU by Nuvo™ is a non-invasive medical device that acquires and displays vital signs of the pregnant woman and her fetus. It measures and processes signals picked up on the abdominal surface using highly sensitive sensors, special electronic circuitry, and processing software. Two types of sensors pick up the signals: ECG-like sensors that pick-up bio-potential signals, and acoustic sensors. The bio-potential (ECG-like) sensors pick up the fECG (of the fetus), the mECG signals (of the pregnant woman) and the acoustic sensors measure the sounds from the pregnant woman's abdomen (PCG -phonocardiogram and fPCG - fetal PCG). The FHR, MHR, and UA tracings are derived from these signals and presented.

INVU by Nuvo™ is an integrated platform that uses a signal acquisition tool to provide input related to fetal heart rate (FHR), maternal heart rate (MHR), to two separate software applications, one for the patient (INVU App) and one for the physician (INVU-Pro application), which also provides uterine activity (UA) tracings. Sensors are incorporated in a belt that is worn on the abdomen of the pregnant woman, where it acquires both biopotential and acoustic signals. The signals are processed at a cloud-server level. The sensors are attached to the pregnant woman's abdomen by a belt (INVU by Nuvo™ sensory band). An integrated electronic module receives, processes and transmits the measured data to algorithmic modules at cloud servers, where the

inputs from the sensors are processed, merged, and sent to the INVU by Nuvo™ (patient) application to display the average FHR and average MHR after a 30 minute (minimum) monitoring session and to the INVU by Nuvo™ Pro (physician) application to display the complete FHR, MHR, and uterine activity data from a monitoring session. A monitoring session can only be scheduled by a health care provider.

The purpose of this special 510(k) is to implement several minor improvements to straps, buckles and LED used in the device. There have also been several minor changes to the software.

Indications for Use

INVU by Nuvo™ is a maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR), maternal heart rate (MHR) and Uterine Activity (UA).

The INVU Sensor Band™ acquires the fetal heart electrocardiogram and maternal heart electrocardiogram signals from abdominal surface electrodes and the fetal phonocardiogram and the maternal phonocardiogram signals from surface acoustic sensors. The FHR, MHR and UA tracings are derived from these signals and presented.

INVU by Nuvo™ is indicated for use by pregnant women who are in their 32nd week of gestation (or later), with a singleton pregnancy.

The INVU by Nuvo™ maternal-fetal monitor is intended for use by healthcare professionals in health care facilities and by the patient in the patient's home, on the order of a physician.

The INVU by Nuvo™ is indicated for antepartum fetal surveillance (i.e. non-stress testing).

This system does not prevent the onset of preterm labor nor will it prevent the occurrence of preterm birth.

Substantial Equivalence

A table comparing the intended use and technological characteristics of the subject and predicate device is provided below.

	Subject Device: INVU by Nuvo	Predicate Device: INVU by Nuvo
510(k) Number	K221046	K210025
Product Code	LQK	LQK
Classification	21 CFR 884.2730	21 CFR 884.2730
Device Type	Maternal-fetal monitor	Maternal-fetal monitor
Prescription Use	Trained medical personnel or patients on order of a physician	Trained medical personnel or patients on order of a physician
Anatomical Site	Maternal abdomen	Maternal abdomen
Target Population	Women who are ≥32 weeks gestation.	Women who are ≥32 gestational weeks with singleton pregnancy.
Intended Environment	Healthcare setting or home	Healthcare setting or home
Use/Reuse	Reusable by a single patient	Reusable by a single patient
Sterility	Non-sterile	Non-sterile

Patient interface	Maternal abdomen connected to surface ECG-like bio-potential sensors and acoustic sensors	Maternal abdomen connected to surface ECG-like bio-potential sensors and acoustic sensors
FHR/MHR/UA Technology	Transabdominal electrocardiography signals and acoustic signals	Transabdominal electrocardiography signals and acoustic signals
FHR/MHR Sensors	bio-potential sensors and acoustic sensors	bio-potential sensors and acoustic sensors
FHR/MHR Sensor Power Source	Rechargeable battery (on band)	Rechargeable battery (on band)
Data Collected from Sensor Array	Fetal Heart Rate, Maternal Heart Rate, Uterine Contractions	Fetal Heart Rate, Maternal Heart Rate, Uterine Activity
Data Transmission	Wireless communication (Bluetooth, Wi-Fi)	Wireless communication (Bluetooth, Wi-Fi), cloud server
Information displayed on	Cloud or mobile based software applications	Cloud or mobile based software applications
Patient Contacting Material	Band fabric: 80% Polyamide and 20% Elastane and TPU [Polyesterbased Thermoplastic Polyurethane] Sensors: Polycarbonate, Polyamide, Elastomer, Silver, Polyurethane, Aluminum, and Stainless Steel. Back buckle: polycarbonate Makrolon 2485 Plastic components: PC Makrolon 2485, TPE - TM4ADT	Band fabric: 80% Polyamide and 20% Elastane and TPU [Polyester-based Thermoplastic Polyurethane] Sensors: Polyamide, Elastomer, Silver, Polyurethane, and Aluminum Back buckle: polycarbonate Makrolon 2485 Plastic components: PA220 (Nylon12)

The primary technological difference between the subject and the predicate device are modifications made to the INVU Sensor band. These changes include changes in material of manufacture, buckles, belt material, band length, and the LED used during device charging. There have been no modifications that affect sensor position or performance. There have also been minor modifications to the accessory components that are supplied with the monitor (ECG gel and electrodes). Lastly, there have also been minor modifications to the mobile app used by the mother-to-be and the web software used by the healthcare professionals to improve user experience. These differences do not raise different questions of safety and effectiveness.

Performance Data

To support the changes to the subject device, a risk analysis and associated verification and validation for the following assessments were provided:

- Biocompatibility testing including cytotoxicity, irritation, and sensitization per the recommendations in the 2020 guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”

- Software documentation and validation per the recommendations in the 2017 guidance document “Deciding When to Submit a 510(k) for a Software Change to an Existing Device”

- Functional testing to demonstrate the straps and buckles have adequate mechanical performance (e.g., mechanical functionality testing and tensile strength testing)

- Electrical resistance testing to demonstrate continued electrical performance of the snapping feature of the sensor.

- Electrical testing including bio-potential frequency response and charge mode testing to demonstrate continued electrical performance of the LED light.

Conclusions

The results of the testing described above demonstrate that the INVU by Nuvo™ is as safe and effective as the predicate device and supports a determination of substantial equivalence.