May 28, 2021

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

Re: K210025
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 27, 2021
Received: April 27, 2021

Dear Janice M. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210025

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 BandTM 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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510(k) SUMMARY

Nuvo-Group Ltd.'s INVU by NUVO™

Submitter

Nuvo-Group Ltd.
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Date Prepared: May 28, 2021

Name of Device: INVU by Nuvo ™
Common or Usual Name: Home Uterine Activity Monitor
Regulation Number: 21 CFR 884.2730
Regulation Name: Home Uterine Activity Monitor
Product Code: LQK
Product Code Name: Home Uterine Activity Monitor
Regulatory Class: II

Predicate Device: Sense4Baby System Model B+ (K143114). The predicate device has been subject to a design-related recall (belt clip defects).

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.

It 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.

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 Comparison

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

Comparison Chart

	Subject Device: INVU by Nuvo™	**Predicate Device: Sense4Baby System Model B+**
510(k) Number	K210025	K143114
Product Code	LQK	LQK, MOH, HGM
Classification	21 CFR 884.2730	21 CFR 884.2730
Device Type	Maternal-fetal monitor	Maternal-fetal monitor
Intended Use/ 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.	The Sense4Baby System Model B+ is indicated for conventional antepartum fetal monitoring applications in pregnancies greater than or equal to 24 weeks gestation. It may be used for antenatal monitoring (e.g., non-stress testing and/or uterine activity monitoring) in a health care setting or home. It is to be used by health care professionals and patients on the order of a physician. Before the Sense4Baby System Model B+ is prescribed for home use, the user (patient) must be instructed/trained in the proper use of the equipment. Home uterine activity monitoring has not been shown to prevent the onset of preterm labor nor will it prevent the occurrence of preterm birth.
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
Intended Environments	Health care setting or home	Health care setting or home
Target Population	Women who are ≥32 gestational weeks with a singleton pregnancy	Women who are ≥24 weeks gestation

	Subject Device: INVU by Nuvo™	Predicate Device: Sense4Baby System Model B+
Patient Interface	Maternal abdomen connected to surface ECG-like bio-potential sensors and acoustic sensors	Maternal abdomen connected to a sensor with Piezo-electric crystals
Data Collected from Sensor Array	Fetal heart rate, Maternal heart rate, Uterine activity	Fetal heart rate, Maternal heart rate, Uterine activity
Data transmission	Wireless communication (Bluetooth, Wi-Fi)	Wireless communication (Bluetooth, Wi-Fi)
Use/Reuse	Reusable by a single patient	Reusable by a single patient
Sterility	Non-sterile	Non-sterile
Technology Employed	Transabdominal electrocardiography signals and acoustic signals	Pulsed Doppler Ultrasound
FHR/MHR/UA Sensors	Bio-potential sensors and acoustic sensors	Piezo-electric Crystals
Information Displayed On	Web or mobile-based software applications	Web-based portal

The subject and the predicate device have similar indications for use statements and intended use- for antenatal monitoring in a health care setting or home environment by the patient, by prescription only.

The subject device is to be utilized in women who are greater than 32 weeks of gestation, whereas the predicate device can be used in subjects who are greater than 24 weeks gestation. Both the subject and predicate device are intended to be used for conventional antepartum monitoring by both the physician and the patient. Both the predicate and subject device are indicated for use for both fetal/maternal heart rate monitoring, and uterine activity monitoring.

The predicate and subject device do also have differences in patient interface, FHR/MHR/UA technology, FHR/MHR/UA sensors and patient contacting material. However, different types of safety and effectiveness questions are not raised by these differences in technological characteristics.

Non-Clinical Performance Data

The following testing is provided to support the safety and performance of the INVU by Nuvo™:

- Electronical testing

- electromagnetic testing (IEC 60601-1-2)
- electrical safety testing (IEC 60601-1 and 60601-1-11)
- battery safety
- external defibrillation safety testing
- testing of the electrical interface and electronic parts
- Bluetooth functionality
- over-temperature protection, safety tests, and relevant use cases

- Functionality testing to evaluate the durability and functionality of the various parts of the device, including hardware and accessories
  - PCB testing
  - Belt electronic testing
  - Short circuit protection testing
  - Mechanical functionality
  - Cable and rubber webbing testing
- Software verification and validation testing
  - INVU Platform (Server) version: 2.0.0
  - INVU Mobile application (Android) version: 2.0.0.5153-STAGE
  - INVU Mobile application (iOS) version: 2.0.0 (1521)-STAGE
  - INVU Pro application version: 2.0.0-39833
  - WSH Firmware version: 2.10.5_7.4
- Cleaning and disinfection information per the recommendations of the 2015 guidance document *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*
- Biocompatibility testing per the recommendations of the 2016 guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* as follows*:*
  - Cytotoxicity – ISO 10993-5:2009/®2014
  - Sensitization – ISO 10993-10:2010
  - Irritation – ISO 10993-10:2010
- Human factors testing per recommendations of the 2016 guidance document *Applying Human Factors and Usability Engineering to Medical Devices*

Clinical Performance Data

The performance of the INVU by Nuvo™ to collect and display MHR/FHR safely and effectively was addressed in K191401. A pivotal clinical study to demonstrate the safe and effective collection and display of uterine activity was performed to collect and digitally record uterine activity data from INVU by Nuvo™, the uterine activity gold standard (IUPC) and the uterine activity standard of care (TOCO) in order to provide evidence of safety and agreement between INVU by Nuvo™ and both the gold standard and the standard of care devices for the assessment of uterine activity.

The study was divided into two phases – a training phase (N=40) and a validation phase (N=80). During the training phase, uterine activity data was collected to "train" the UA algorithm to identify uterine contractions. This was followed by the validation phase, which validated the final algorithm for identifying and displaying uterine contractions.

The results of this testing showed that the INVU by Nuvo™ platform provided reliable uterine activity (UA) data by demonstrating a comparable performance of INVU by Nuvo™ to that of the gold standard, IUPC. INVU™ met the performance goal of achieving a lower 95% confidence bound of the positive percent agreement that is greater than 75%. INVU™ presented a positive percent agreement of 84.80% (95% CI: [81.58%; 88.02%]) compared to IUPC. In comparison, the TOCO device showed positive percent agreement of 37.50% (95% CI: [28.23%;46.77%]). INVU™ presented a false positive rate of 24.28% (95%CI: [20.46%;28.11%]) compared to IUPC, while the TOCO device showed a false rate of 10.69% (95%CI: [5.65%;15.72%]). These data demonstrate that INVU™ is comparable to the standard of care TOCO device and meets the required accuracy for its intended use in populations of pregnant women ages between 18-50 of at least 32 weeks gestation. No device-related adverse events were observed during the validation study.

Conclusions

The results of the performance testing described above demonstrate that the INVU by Nuvo™ is as safe and effective as Sense 4 Baby and supports a determination of substantial equivalence.