March 27, 2020

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

Re: K191401
Trade/Device Name: PregSense™
Regulation Number: 21 CFR 884.2730
Regulation Name: Home Uterine Activity Monitor
Regulatory Class: II
Product Code: LQK
Dated: March 23, 2020
Received: March 23, 2020

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); 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,

for Monica D. Garcia, Ph.D.
Acting 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)*
K191401

Device Name
PregSense™

Indications for Use *(Describe)*

PregSense is a maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR) and maternal heart rate (MHR). The PregSense acquires and displays the FHR and MHR tracings from abdominal surface electrodes that pick up the fetal heart biopotential and maternal heart biopotential signal, and from surface acoustic sensors that pick up the fetal PCG (fPCG; phonocardiogram) and the maternal PCG (mPCG; phonocardiogram) signals.

PregSense is indicated for use by pregnant women who need documentation of fetal heart rate activity, and who are in their 32nd week of gestation (or later), with a singleton pregnancy. PregSense is intended to be used for a maximum of five minutes.

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

The PregSense is not intended for use in critical care situations or in laboring patients or those patients hospitalized for or suspected to have preterm labor.

PregSense is not intended to be used for antepartum monitoring (e.g., non-stress testing).

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

K191401 - PregSense™

Submitter

Nuvo-Group Ltd.
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Date Prepared: March 26, 2020

Name of Device: PregSense™
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

PregSense™ is a non-invasive medical device that acquires and displays vital signs of the pregnant woman and of her fetus. It measures and processes signals picked up on the abdominal surface using sensors, electronic circuitry and processing software. Two types of sensors pick up the signals: electrocardiogram (ECG)-like sensors that capture bio-potential signals, and acoustic sensors. The bio-potential (ECG-like) sensors capture fECG (heartrate of the fetus) and mECG signals (heartrate of the pregnant woman). The acoustic sensors measure the sounds from the pregnant woman's abdomen, (PCG -phonocardiogram and fPCG -fetal PCG). Monitoring of the fetal and maternal heart rate using PregSense is limited to a five-minute session.

PregSense™ is an integrated platform that uses a signal acquisition tool to provide input to two separate software applications, one for the patient (PregSense™ ME) and one for the physician (PregSense™ MD). The sensors are incorporated in a belt (PregSense™ Belt) that is worn on the abdomen of the pregnant woman, where it acquires both biopotential and acoustic signals. The signals are processed at the cloud-server level where the inputs from the sensors are processed, merged and downloaded to the mobile devices of the pregnant woman and her health care provider. The PregSense™ ME application (for the patient) allows the pregnant woman to view the average maternal and fetal heart rate after a

five minute session has been completed and PregSense™-MD application (for the health care provider) allows the health care provider to view the complete fetal and maternal heart rate data from the five minute session online and remotely via the internet. A monitoring session can only be initiated by a health care provider.

Indications for Use

PregSense is a maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR) and maternal heart rate (MHR). The PregSense acquires and displays the FHR and MHR tracings from abdominal surface electrodes that pick up the fetal heart biopotential and maternal heart biopotential signal, and from surface acoustic sensors that pick up the fetal PCG (fPCG; phonocardiogram) and the maternal PCG (mPCG; phonocardiogram) signals.

PregSense is indicated for use by pregnant women who need documentation of fetal heart rate activity, and who are in their 32nd week of gestation (or later), with a singleton pregnancy. PregSense is intended to be used for a maximum of five minutes.

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

The PregSense is not intended for use in critical care situations or in laboring patients or those patients hospitalized for or suspected to have preterm labor.

PregSense is not intended to be used for antepartum monitoring (e.g., non-stress testing).

Substantial Equivalence Comparison

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

Comparison Chart

	Subject Device: **Nuvo's PregSense System**	**Predicate Device:** **Sense4Baby System Model B+**
510(k) Number	K191401	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	PregSense is a maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR) and maternal heart rate (MHR). The PregSense acquires and displays the FHR and MHR tracings from abdominal surface electrodes that pick up the	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

	Subject Device: **Nuvo's PregSense System**	**Predicate Device:** **Sense4Baby System Model B+**
	fetal heart biopotential and maternal heart biopotential signal, and from surface acoustic sensors that pick up the fetal PCG (fPCG; phonocardiogram) and the maternal PCG (mPCG; phonocardiogram) signals. PregSense is indicated for use by pregnant women who need documentation of fetal heart rate activity, and who are in their 32nd week of gestation (or later), with a singleton pregnancy. PregSense is intended to be used for a maximum of five minutes. The PregSense maternal-fetal monitor is intended for use in the antepartum period by healthcare professionals in health care facilities and by the patient in the patient's home, on the order of a physician. The PregSense is not intended for use in critical care situations or in laboring patients or those patients hospitalized for or suspected to have preterm labor. PregSense is not intended to be used for antepartum monitoring (e.g., non-stress testing).	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 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	Medical personnel or patients on order of physician	Medical personnel or patients on order of physician
Intended Environments	Health care setting or home	Health care setting or home
Target Population	Women who are ≥32 gestational weeks with singleton pregnancy	Women who are ≥24 weeks gestation
Patient Interface	Maternal abdomen connected to surface ECG-like bio-potential sensors	Maternal abdomen connected to sensor with Piezo-electric crystals

	Subject Device: **Nuvo's PregSense System**	**Predicate Device:** **Sense4Baby System Model B+**
	and acoustic sensors	
Data Collected from Sensor Array	Fetal heart rate, Maternal heart rate	Fetal heart rate, Maternal heart rate, Uterine activity
Technology Employed	Transabdominal electrocardiography signals and acoustic signals	Pulsed Doppler Ultrasound
Monitoring Session	5 minutes	30 minutes
Information Displayed On	Cloud or mobile based software applications	Web based portal

The subject and the predicate device have different indications for use statements, but have the same 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 the 24 weeks of gestation. Both the subject and predicate device are intended to be used for conventional antepartum monitoring by both the physician and the patient. The predicate device is indicated for use for both fetal/maternal heart rate monitoring and uterine activity monitoring, whereas the subject device is indicated for fetal/maternal heart rate monitoring only. However, as both the subject and predicate device are intended to be used for fetal/maternal heart rate monitoring, the lack of uterine activity monitoring does not raise different questions of safety and effectiveness as it pertains to the function of the device. In addition, the subject device is intended to be used for a maximum of five minutes, rather than 30 minutes as indicated for the predicate device. This is not a new intended use, as both the subject and predicate device are used to document fetal and maternal heart rate activity.

The subject and predicate devices have different technological characteristics. The FHR/MHR technology (i.e., ECG vs pulsed doppler ultrasound) of the subject and predicate device are different, as are the related hardware components associated with these different technologies. In addition, the subject device does not contain uterine activity monitoring technology. Finally, the method of data display between the subject and predicate device is different, with the subject device using a cloud-based service and software apps and the predicate device using a web based portal. However, different types of safety and effectiveness questions are not raised by these differences in technological characteristics.

Non-Clinical Performance Data

The following non-clinical performance testing was provided to support the performance of PregSense™:

- Electronical testing
  - electromagnetic testing (IEC 60601-1-2),
  - electrical safety testing (IEC 60601-1),
  - 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
  - Velcro degradation
  - ECG acquisition/processing/detection/classification per 60601-2-27 and 606001-2-47
- Software verification and validation testing for the PregSense ME App, Software version: 0.40.1.3669; PregSense MD App, Software version: 0.2 (117); PregSense WSH firmware version: 0.123; and the PregSense Server, Software version 0.1.90 per the recommendations of the 2005 guidance document *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices*
- 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 the recommendations of the 2016 guidance document *Applying Human factors and Usability Engineering to Medical devices*

Clinical Performance Data

Two clinical studies were performed using the belt with embedded sensors and associated software for analysis: a feasibility study and a pivotal study. The feasibility study was conducted to assess the feasibility and safety of PregSense™ system. The pivotal trial was conducted in order to demonstrate

that the PregSense™ performs appropriately for its intended use. The feasibility and pivotal trials were conducted using the device in thirty-minute sessions. However, the data used to support the safety and effectiveness of the subject device was limited to five minutes.

During the feasibility study, a total of 76 subjects participated for which a total of 510 recording sessions were executed. Female subjects aged ≥ 18 years and ≤ 50 years with a singleton pregnancy between 20–40 weeks of gestation and who were capable of signing informed consent were included in the study. No adverse events, procedure-related or device-related, were reported during the study. The results of the feasibility study showed that the overall detection percentage was > 70% for the overall population and 90% (±11.3) for those at least 32 weeks of gestation. Therefore, the pivotal study was performed in women at 32 weeks or more.

A pivotal clinical study in four healthcare settings (two in the United States and two outside the United States) to permit comparison to a "standard of care" monitoring device (CTG) was performed in 149 subjects. Because this type of "standard of care" monitoring could not be performed in a home environment, use in a healthcare setting was required. To ensure the device will perform appropriately when the belt is worn by the patient at home, a usability study was performed with lay users. Using Bland-Altman Limits of Agreement, the pivotal clinical testing for the complete 30-minute session demonstrated that for FHR, 97.08% of all differences lie between the 95% agreement limits of [-8.84, 8.24] bpm in the 149 subjects with no adverse events reported. In addition, the pivotal clinical testing demonstrated that for MHR, 95.31% (48241/50616) of all differences lie between the 95% agreement limits of [-5.30, 5.86] bpm.

As the duration of data collection of the PregSense system is limited to 5 minutes, an additional analysis of the limits of agreement using only 5 minutes of outputted data post-calibration showed narrower limits of agreement than originally reported using the entire 30-minute data collection: the lower limit of the 95% confidence interval of the lower agreement bound is -7.47 bpm and the upper limit is 8.16 bpm. Furthermore, 96.64% of the differences fall between the limits of agreement.

Together, the completed clinical and usability testing demonstrate that the device accuracy is acceptable and that lay users can use the device successfully.

Conclusions

The results of the performance testing described above demonstrate that the PregSense device is as safe and effective as the predicate device and supports a determination of substantial equivalence.