

## Indications for Use

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 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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