DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
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*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).

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

X 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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