August 10, 2026

Datex Ohmeda, Inc.
Shiwani Zalpuri
Manger, Regulatory Affairs
3114 N Grandview Blvd.
Waukesha, Wisconsin 53188

Re: K254036
Trade/Device Name: Novii+ Wireless Patch System
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal Monitoring System and accessories
Regulatory Class: II
Product Code: HGM
Dated: July 9, 2026
Received: July 9, 2026

Dear Shiwani Zalpuri:

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 (the 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 available 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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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)*
K254036

Device Name
Novii+ Wireless Patch System

Indications for Use *(Describe)*

The Novii+ Pod is an antepartum and intrapartum Maternal/Fetal Monitor that non-invasively measures fetal heart rate (FHR), uterine activity (UA) and maternal heart rate (MHR). The Novii+ Pod acquires the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the Pod also acquires the UA tracing from the uterine electromyography (EMG) signal and the MHR tracing from the maternal ECG signal (mECG). The Pod is indicated for use on women who are at 34 weeks and 0/7 days and greater with singleton pregnancies, using surface electrodes on the maternal abdomen.

The Novii Patch is an accessory to the Novii+ Pod that connects directly to the Novii+ Pod and contains the surface electrodes that attach to the abdomen.

The Novii+ Interface is an accessory to the Novii+ Pod which provides a means of interfacing the wireless output of the Novii+ Pod to the transducer inputs of a Maternal/Fetal Monitor. The Novii+ Interface enables signals collected by the Novii+ Pod to be printed and displayed on a Maternal/Fetal Monitor and sent to a central network, if connected.

The Novii+ Pod Maternal/Fetal Monitor and its accessories are intended for use by healthcare professionals in a clinical setting

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K254036

In accordance with 21 CFR 807.92 the following summary information is provided:

Date:	10 August 2026
Owner/Submitter:	GE HealthCare (dba Datex- Ohmeda, Inc.) 3114 N. Grandview Blvd Waukesha, WI 53188
Primary Contact Person:	Shiwani Zalpuri Regulatory Affairs Manager GE HealthCare Phone: +91 9871090801 Email: shiwani.zalpuri@gehealthcare.com
Secondary Contact Person:	Isabel McGann Regulatory Affairs Director GE HealthCare Phone: 720-447-0747 Email: Isabel.mcgann@gehealthcare.com
Device Trade Name:	Novii+ Wireless Patch System
Common/Usual Name:	Perinatal monitoring system and accessories
Regulation Number:	21 CFR 884.2740
Regulation Name:	Perinatal monitoring system and accessories
Classification:	Class II
Product Code:	HGM (System, Monitoring, Perinatal)
Predicate Device:	Novii+ Wireless Patch system (K231964) The predicate device has not been subject to a design-related recall.
Device Description:	The Novii+ Wireless Patch System (Novii+ system) is battery-powered Maternal/Fetal Monitor that measures abdominal fetal heart rate (FHR), abdominal maternal heart rate (MHR), and abdominal uterine activity (UA) and sends data to a previously cleared Corometrics 259cx (K072976) or a Corometrics 174 maternal/fetal monitor (K993751) via Novii+ Pod. The monitor enables the abdominal electrophysiological signal to be picked up from three different positions on the maternal abdomen using the 5 electrodes on the Novii Patch. The Novii+ Pod acquires the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the Pod also acquires the UA tracing from the uterine electromyography (EMG) signal and the MHR tracing from the maternal ECG signal (mECG). The Novii+ Pod is a battery-powered device that the patient wears for surveillance of fetal and maternal well-being. The Novii+ Pod is indicated for use on women who are at 34 weeks and 0/7 days and greater with singleton pregnancies. This Traditional 510(k) is to add an alternate, equivalent patch to the previously cleared Novii+ Wireless Patch System (K231964). This alternate patch is interchangeable as it is equivalent in form, fit and function to the predicate patch.

Indications for Use:	The Novii+ Pod is an antepartum and intrapartum Maternal/Fetal Monitor that non-invasively measures fetal heart rate (FHR), uterine activity (UA) and maternal heart rate (MHR). The Novii+ Pod acquires the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the Pod also acquires the UA tracing from the uterine electromyography (EMG) signal and the MHR tracing from the maternal ECG signal (mECG). The Pod is indicated for use on women who are at 34 weeks and 0/7 days and greater with singleton pregnancies, using surface electrodes on the maternal abdomen. The Novii Patch is an accessory to the Novii+ Pod that connects directly to the Novii+ Pod and contains the surface electrodes that attach to the abdomen. The Novii+ Interface is an accessory to the Novii+ Pod which provides a means of interfacing the wireless output of the Novii+ Pod to the transducer inputs of a Maternal/Fetal monitor. The Novii+ Interface enables signals collected by the Novii+ Pod to be printed and displayed on a Maternal/Fetal Monitor and sent to a central network, if connected. The Novii+ Pod Maternal/Fetal Monitor and its accessories are intended for use by healthcare professionals in a clinical setting.

COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

A comparison of the intended use and technological features of the subject and predicate device is provided in Table 1 below.

Table 1: High-level Comparison of Subject Device to Predicate Device

Specification	Predicate Device Novii+ Wireless Patch System K231964	Subject Device Novii+ Wireless Patch System K254036	Discussion of Differences
Indications for Use	The Novii+ Pod is an antepartum and intrapartum Maternal/Fetal Monitor that non-invasively measures fetal heart rate (FHR), uterine activity (UA) and maternal heart rate (MHR). The Novii+ Pod acquires the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the Pod also acquires the UA tracing from the uterine electromyography (EMG) signal and the MHR tracing from the maternal ECG signal (mECG). The Pod is indicated for use on women who are at 34 weeks and 0/7 days and greater with singleton pregnancies, using surface electrodes on the maternal abdomen.	The Novii+ Pod is an antepartum and intrapartum Maternal/Fetal Monitor that non-invasively measures fetal heart rate (FHR), uterine activity (UA) and maternal heart rate (MHR). The Novii+ Pod acquires the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the Pod also acquires the UA tracing from the uterine electromyography (EMG) signal and the MHR tracing from the maternal ECG signal (mECG). The Pod is indicated for use on women who are at 34 weeks and 0/7 days and greater with singleton pregnancies, using surface electrodes on the maternal abdomen. The Novii Patch is an accessory to the Novii+ Pod that connects directly to the	Identical

Specification	Predicate Device Novii+ Wireless Patch System K231964	Subject Device Novii+ Wireless Patch System K254036	Discussion of Differences
	The Novii Patch is an accessory to the Novii+ Pod that connects directly to the Novii+ Pod and contains the surface electrodes that attach to the abdomen. The Novii+ Interface is an accessory to the Novii+ Pod which provides a means of interfacing the wireless output of the Novii+ Pod to the transducer inputs of a Maternal/Fetal Monitor. The Novii+ Interface enables signals collected by the Novii+ Pod to be printed and displayed on a Maternal/Fetal Monitor and sent to a central network, if connected. The Novii+ Pod Maternal/Fetal Monitor and its accessories are intended for use by healthcare professionals in a clinical setting.	Novii+ Pod and contains the surface electrodes that attach to the abdomen. The Novii+ Interface is an accessory to the Novii+ Pod which provides a means of interfacing the wireless output of the Novii+ Pod to the transducer inputs of a Maternal/Fetal Monitor. The Novii+ Interface enables signals collected by the Novii+ Pod to be printed and displayed on a Maternal/Fetal Monitor and sent to a central network, if connected. The Novii+ Pod Maternal/Fetal Monitor and its accessories are intended for use by healthcare professionals in a clinical setting.	
Measured Parameters	• Fetal Heart Rate (FHR) • Maternal Heart Rate (MHR) • Uterine Activity (UA)	• Fetal Heart Rate (FHR) • Maternal Heart Rate (MHR) • Uterine Activity (UA)	Identical
Anatomical Sites	Trans-abdominal	Trans-abdominal	Identical
Environment of Use	Healthcare professionals in a clinical setting	Healthcare professionals in a clinical setting	Identical
Patient Population	34 weeks and 0/7 days and greater with singleton pregnancies	34 weeks and 0/7 days and greater with singleton pregnancies	Identical
Pod	The Novii+ Pod connects to each electrode of the patch via Pogo pins. The pod has an analogue front end connected to each electrode that is made up of 4 instrumentation amplifiers and associated electronic bandpass filters. The Novii+ Pod has a dual tone color (Purple and white).	The Novii+ Pod connects to each electrode of the patch via Pogo pins. The pod has an analogue front end connected to each electrode that is made up of 4 instrumentation amplifiers and associated electronic bandpass filters. The Novii+ Pod has a dual tone color (Purple and white).	Identical

Specification	Predicate Device Novii+ Wireless Patch System K231964	Subject Device Novii+ Wireless Patch System K254036	Discussion of Differences
	The Novii+ Pod is not backward compatible and cannot connect to original Novii Interface (K140862).	The Novii+ Pod is not backward compatible and cannot connect to original Novii Interface (K140862).	
Novii Patch	The Novii Patch is made of 5 Silver/silver chloride electrodes that are printed on Polyethylene terephthalate (PET) substrate. The Patch has a plastic clip with magnets to hold the Novii+ Pod in place. Patch: - Single use - 5 Silver/Silver Chloride electrodes on PET substrate with silver tracks and pads - Latex / PVC free The Novii Patch is backward compatible and can connect to original Novii Pod (K140862) and the Novii+ Pod.	The alternate Novii Patch is made of 5 Silver/silver chloride electrodes that are printed on Polyethylene terephthalate (PET) substrate. The Patch has a plastic clip with magnets to hold the Novii+ Pod in place. Patch: - Single use - 5 Silver/Silver Chloride electrodes on PET substrate with silver tracks and pads - Latex / PVC free The Novii Patch is backward compatible and can connect to original Novii Pod (K140862) and the Novii+ Pod.	**Different.**
Supported Monitors	GE Corometrics Maternal / Fetal Monitor	GE Corometrics Maternal / Fetal Monitor	Identical
Alerts	Interface provides the following alerts: - Patient out of Bluetooth range - Low Pod battery - MHR/FHR coincidence - Pod removed from patch - Pod not returned to charging bay - Patch electrode detached / broken pin - Patch not GEHC genuine	The Interface provides the following alerts: - Patient out of Bluetooth range - Low Pod battery - MHR/FHR coincidence - Pod removed from patch - Pod not returned to charging bay - Patch electrode detached / broken pin - Patch not GEHC genuine	Identical
Data Interface (Wireless) Interoperability	The Novii+ Pod and Interface connect wirelessly using Bluetooth version 4.0. Input: Bluetooth Class 1.5, V4.0 real/time continuous, from Novii™ Pod. Modified Series Protocol	The Novii+ Pod and Interface connect wirelessly using Bluetooth version 4.0. Input: Bluetooth Class 1.5, V4.0 real/time continuous, from Novii™ Pod. Modified Series Protocol Irda interface to initiate authentication and Bluetooth pairing	Identical

Specification	Predicate Device Novii+ Wireless Patch System K231964	Subject Device Novii+ Wireless Patch System K254036	Discussion of Differences
	Irda interface to initiate authentication and Bluetooth pairing		

The subject and predicate device have identical indications for use statements and have the same intended use – non-invasive monitoring of fetal heart rate, maternal heart rate, and uterine activity. The subject device (Novii+ Wireless Patch System) includes an alternate patch that has similar fundamental scientific technology to the predicate device (Novii Wireless Patch system) . It maintains the predicate device's functionality, performance and clinical workflows. The inclusion of alternate patch does not raise new questions of safety and effectiveness and is evaluated through non-clinical performance testing as discussed below.

PERFORMANCE TESTING

Summary of Non-Clinical Performance Testing:

Bench testing related to performance as part of the alternate patch qualification such as electrical performance, mechanical performance, electromagnetic compatibility, electrical safety, and biocompatibility was conducted on the Novii+ Wireless Patch System demonstrating the design meets the specifications as discussed below:

EMC/Electrical Safety/Wireless

- The Novii+ Wireless Patch System meets the EMC requirements described in IEC 60601-1-2 Edition 4.0 2014-02 "*Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*" and 2022 FDA Guidance "*Electromagnetic Compatibility (EMC) of Medical Devices*".
- The Novii+ Wireless Patch System meets the electrical safety requirements of IEC 60601-1:2012 "*Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Edition 3.1*".
- The Novii+ wireless patch system (the Novii+ Pod and Patch patient contact parts at the time of defibrillation) was tested for misuse or emergency use of the defibrillator on patient per the requirements of IEC 60601-1: *Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance* clause 8.5.5 as applicable for the defibrillation.
- Wireless testing was leveraged from the predicate device as there is no change to Novii+ Pod.

Biocompatibility

The Novii+ Wireless Patch System follows the 2023 FDA Biocompatibility guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff" and ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process. The testing data demonstrates that the subject device is not cytotoxic, non-sensitizing, and non-irritating.

Reprocessing

The Novii+ Wireless Patch System follows the 2015 FDA guidance "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff*". Since there is no change to the reusable components, Novii+ Pod and Interface, the reprocessing validation is leveraged from the predicate device.

Software and Cybersecurity

Since there is no change to the device software and firmware in Novii+ Pod and Interface, the software and cybersecurity documentation is leveraged from the predicate device.

Human Factors

Since there are no changes to the Novii+ Pod and Interface and the device use with inclusion of alternate patch, human factors testing is leveraged from the predicate device.

CONCLUSION:

The results of the testing described above demonstrate that the Novii+ Wireless Patch System is as safe and effective as the predicate device and supports a determination of substantial equivalence.