



December 8, 2023

Datex Ohmeda  
Isabel McGann  
Director, Regulatory Affairs  
9900 Innovation Drive  
Wauwatosa, WI 53226

Re: K231964  
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: November 8, 2023  
Received: November 8, 2023

Dear Isabel McGann:

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: 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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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](mailto: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,  
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## Indications for Use

510(k) Number (if known)

K231964

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.

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## 510(k) Summary – K231964

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

<b>Date Prepared:</b>	07 DEC 2023
<b>Owner/Submitter:</b> 21 CFR 807.92(a)(1)	GE HealthCare (dba Datex- Ohmeda, Inc.) 9900 Innovation Drive Wauwatosa, WI 53226
<b>Primary Contact Person:</b>	Isabel McGann Regulatory Affairs Director GE HealthCare Email: Isabel.mcgann@gehealthcare.com
<b>Secondary Contact Person:</b>	Shiwani Zalpuri Regulatory Affairs Program Manager GE HealthCare Email: Shiwani.zalpuri@gehealthcare.com
<b>Device Trade Name:</b> 21 CFR 801.92(a)(2)	Novii+ Wireless Patch System
<b>Common/Usual Name:</b>	Perinatal monitoring system and accessories
<b>Regulation Name:</b>	Perinatal monitoring system and accessories
<b>Regulation Number:</b>	21 CFR 884.2740
<b>Classification:</b>	II
<b>Product Code:</b>	HGM (System, Monitoring, Perinatal)
<b>Predicate Device:</b> 21 CFR 807.92(a)(3)	Monica Novii Wireless Patch system (K140862) The predicate device has not been subject to a design-related recall.
<b>Predicate Device Manufacturer</b>	Monica Healthcare Ltd
<b>Device Description:</b> 21 CFR 807.92(a)(4)	<p>The Novii+ Wireless Patch System (Novii+ system) is a battery-powered maternal-fetal monitoring system that measures abdominal fetal heart rate (FHR), abdominal uterine activity (UA), and abdominal maternal heart rate (MHR). The Novii+ Wireless Patch system is designed as an ambulatory device for the monitoring of a pregnant mother. 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 monitor filters the abdominal signals, converts the abdominal electrophysiological data into a digital format and then processes it in real time to extract the fetal heart rate, maternal heart rate and uterine activity. The result of the processing is transmitted via a Bluetooth connection to the Novii+ Interface device which is an accessory to the Novii+ Pod.</p> <p>The Novii+ Pod (proposed device) is indicated for use on women who are at 34 weeks and 0/7 days and greater with singleton pregnancies with cephalic fetal presentation.</p>

<p><b>Indications for Use:</b> 21 CFR 807.92(a)(5)</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>The Novii+ Pod Maternal/Fetal Monitor and its accessories are intended for use by healthcare professionals in a clinical setting.</p>
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**COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE:  
21CFR807.92(a)(6)**

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**

Specification	Predicate Device Monica Novii Wireless Patch System K140862	Subject Device Novii+ Wireless Patch System K231964	Discussion of Differences
<b>Indications for Use</b>	The Monica Novii Pod is an intrapartum maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR), uterine activity (UA) and maternal heart rate (MHR). The Novii Pod acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface	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,	This difference does not raise different questions of safety and effectiveness and can be addressed through performance testing.

Specification	Predicate Device Monica Novii Wireless Patch System K140862	Subject Device Novii+ Wireless Patch System K231964	Discussion of Differences
	<p>electrodes, the Pod also acquires and displays 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 &gt;36 completed weeks, in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.</p> <p>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.</p> <p>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 CTG Fetal monitor. The Novii Interface enables signals collected by the Novii Pod to be printed and displayed on a CTG Fetal Monitor and sent on to a central network, if connected.</p> <p>The Novii Pod maternal-fetal monitor and its accessories are intended for use by healthcare professionals in a clinical setting.</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>The Novii+ Pod Maternal/Fetal Monitor and its accessories are intended for use by healthcare professionals in a clinical setting.</p>	
<b>Patient Population</b>	Intrapartum > 36 completed weeks for labor & delivery with singleton pregnancies	34 weeks and 0/7 days and greater with singleton pregnancies	<p>Different</p> <p>The Novii+ Pod with its modified algorithm can be used to monitor patient from 33 completed weeks</p>

Specification	Predicate Device Monica Novii Wireless Patch System K140862	Subject Device Novii+ Wireless Patch System K231964	Discussion of Differences
			(34 weeks and 0/7 days and greater), described as the preterm patient population.  This difference does not raise different questions of safety and effectiveness and can be addressed through performance testing.
<b>Pod</b>	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.  Original Novii pods are solid color  Novii Pods are not compatible with Novii+ Interface	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) with slight dimensional difference  The Novii+ Pod is not backward compatible	Similar
<b>Patch</b>	The Novii Patch is made electrodes that are hold together in place by a substrate. The Patch has a plastic clip with magnets to hold in place the Novii Pod. Patch: - Single use - 5 electrodes on a substrate - Latex / PVC free - Gel quantity per electrode: 300mg	The Novii Patch is made electrodes that are hold together in place by substrate. The Patch has a plastic clip with magnets to hold in place the Novii+ Pod. Patch: - Single use - 5 electrodes on a substrate - Latex / PVC free - Gel quantity per electrode: 385mg	Similar
<b>Supported Monitors</b>	GE Corometrics Maternal / Fetal Monitor (K072976) Philips Avalon Monitor (K140535)	GE Corometrics Maternal / Fetal Monitor (K072976)	Similar  Novii+ Wireless Patch System does not support Philips Avalon Monitor



Specification	Predicate Device Monica Novii Wireless Patch System K140862	Subject Device Novii+ Wireless Patch System K231964	Discussion of Differences
Alerts	The Interface alerts for confirmation of features and confirmation of charging.	The Interface alerts for confirmation of features and confirmation of charging. New Alert: - Patch electrode detached / broken pin	Different. The new alerts included in the subject device do not raise different questions of safety and effectiveness.
Data Interface (Wireless) Interoperability	The Novii Pod and Interface connect wirelessly using Bluetooth version 2.0. Input: Bluetooth Class 1.5, V2.0 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	Similar

The subject and predicate device have similar indications for use statements and have the same intended use – non-invasive monitoring of fetal heart rate, maternal heart rate, and uterine activity. The Novii+ Pod software has been modified to work on patients who are at 34 weeks and 0/7 days and greater with singleton pregnancies with cephalic fetal presentation described as the preterm patient population as indicated in the modified indications for use. This difference in intended use population does not raise different questions of safety and effectiveness.

The proposed device (Novii+ Wireless Patch System) 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 Novii+ Wireless Patch System consists of minor updates to the existing version of the system (Novii system). Additionally non-significant changes were made the Novii system (e.g., update to the Pogo pin design, increase in quantity of gel in each electrode, changes in the patch PET shape, changes to the color, dimension and interface compatibility of the Pod). The different technological features of the subject device do not raise different questions of safety and effectiveness.

**PERFORMANCE DATA: Determination of Substantial Equivalence 21 CFR 807(b)(1)**

Summary of Non-Clinical Tests:

The Novii+ Wireless Patch System was tested to and complies with applicable voluntary standards. The Novii+ Wireless Patch System was tested to assure that the device meets its design specifications. Testing included all new or modified features.

### Bench Testing

Bench testing related to software, hardware and performance including applicable consensus standards was conducted on the Novii+ Wireless Patch System demonstrating the design meets the pre-defined specifications.

Per the FDA guidance document entitled “Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions; Guidance for Industry and Food and Drug Administration Staff, Document issued on December 20, 2019”, the following was verified:

- System Verification
  - Pod and patch interface
  - FECG/FHR quality indicator
  - Confirmation of alerts
  - Bluetooth connectivity
  - Data transfer to GE HealthCare Corometrics monitors
- Testing Wireless Interfaces
- Pod Algorithm Verification
- Hardware Bench Testing
- Manuals Bench Testing
- Packaging Bench Testing
- Reprocessing Bench Testing
- Human Factors/Usability Testing

### 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". Compliance according to the “Electromagnetic Compatibility (EMC) of Medical Devices Guidance for Industry and Food and Drug Administration Staff, issued on June 6, 2022”. The Novii+ Wireless Patch System has been evaluated for electromagnetic compatibility and potential risks from common emitters in the Novii+ Wireless Patch System Solution environment, such as radio frequency identification readers, by testing per the AIM 7351731 Rev 2.00 "Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers" standard.

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 as 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. The device passed the applicable test cases such as common mode test and energy reduction mode tests with no impact to patient safety. The differential mode test at the higher voltage levels as prescribed by the standard protocol is not applicable based on the device intended use and hence was tested and found to be passing as per applicable test conditions. As the product is not designed to be completely defibrillation proof and also not intended to be used to monitor the maternal and fetal parameters at the time of defibrillation, the device is contraindicated for use with defibrillators.

Wireless performance data was provided related to:

- Radio Frequency Wireless Technology in Medical Devices; Guidance for Industry and Food and Drug Administration Staff, Document issued on: August 14, 2013
- IEEE ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence

### Biocompatibility

The Novii+ Wireless Patch System follows the 2020 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” and the following standards:

- ISO 17664 Second edition 2017-10 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
- 17664-2 First edition 2021-02 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.

Reprocessing efficacy validation has been conducted in accordance with the documented reprocessing instructions of the Novii+ Wireless Patch System. The reprocessing efficacy validation met the acceptance criteria for the reprocessing efficacy validation tests.

### Human Factors

The Novii+ Wireless Patch System follows the 2016 FDA guidance – “Applying Human Factors and Usability Engineering to Medical Devices; Guidance for Industry and Food and Drug Administration Staff”, and the following standards:

- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]

### Software

The Novii+ Wireless Patch System adheres to FDA software guidance documents as outlined in this submission including the following:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Document issued on May 11, 2005
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on January 11, 2002
- Off-The-Shelf Software Use in Medical Devices; Guidance for Industry and Food and Drug Administration Staff, Document issued on September 27, 2019
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff issued April 8, 2022
- FDA's Policy, Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act issued March 29, 2023
- Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, Document issued on September 6, 2017

Software testing was conducted, and documentation was provided per 2005 FDA Guidance- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is considered as a "Major" level of concern. Software standard - "IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes" and risk management standard - "ISO 14971 Third Edition 2019-12, Medical devices - Application of risk management to medical devices" were also applied to the design.

### Cybersecurity

Patient safety, security, and privacy risks have been addressed in the design and development of Novii+ Wireless Patch System including a Security Risk Assessment, Threat model and Penetration testing. This includes system integrity controls, access controls, audit controls, network controls, and remote service controls which address the general principles and security capabilities outlined in the 2023 FDA guidance - "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions". Additionally, in accordance with the FDA's Policy, Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act, a plan to monitor, identify and address, in a reasonable time, postmarket vulnerabilities and exploits and an S-BOM is provided.

### Summary of Clinical testing: 21 CFR 807.92(b)(2)

A clinical study was performed to determine the Novii+ Wireless Patch System's equivalence to Doppler Fetal Heart Rate (FHR), TOCO Uterine Activity (UA) and SpO2 Maternal Heart Rate (MHR) devices for pre-term patients ( $\geq 34$  weeks + 0/7 days) in terms of accuracy and reliability.

Overview of the Clinical study:

30 subjects between 34 weeks + 0/7 days gestation through 36 weeks + 6/7 days gestation were enrolled: 14 subjects with threatened pre-term labor (non-laboring) and 16 subjects with pre-term labor and delivery. The acceptance criteria and results are summarized below.

**FHR :**

The mean percent agreement (PA) for FHR between the Novii+ Wireless Patch System and the predicate Doppler FHR was 88.08% with 95% lower limit confidence interval (CI) of 83.45%, above the 80% threshold set to demonstrate equivalence. In addition, for FHR the Deming Slope and Intercept were 1.02 and -3.18 Beats Per Minute (BPM), respectively. The 95% two-sided CIs for the slope fall within 0.958 and 1.042, and the intercept falls within -10 and 10 BPM which are the ranges set to demonstrate equivalence.

**MHR:**

The mean PA for MHR between the Novii+ Wireless Patch System and the comparator SpO2 MHR was 98.15% with 95% lower limit CI of 97.26%, above the 80% threshold set to demonstrate equivalence. In addition, for MHR the Deming Slope and Intercept were 1.01 and -1.18 BPM, respectively. The 95% two-sided CIs for the slope fall within 0.958 and 1.042, and the intercept falls within -10 and 10 BPM which are the ranges set to demonstrate equivalence.

The relative interpretability (RI) and mean positive percent agreement (PPA) for UA between the Novii+ Wireless Patch System and the TOCO UA were 100% and 89.5%, respectively. The 95% lower limit CIs were 100% and 85.48% for RI and PPA. These values are both above the 80% threshold set to demonstrate equivalence.

Additional re-assessment was done for the above clinical data, where the lower bounds of the two-sided 95% confidence intervals, primary end point values and pass criteria are summarized below in Table 2.

**Table 2: Lower Bounded Statistics**

	Criteria (Lower limit of 95% two-sided CI)	PA (Lower limit of 95% two-sided CI)	RI (Lower limit of 95% two-sided CI)	PPA (Lower limit of 95% two-sided CI)	Summary
FHR	>80%	83.45	--	--	PASS
MHR	>80%	97.26	--	--	PASS
UA/UC	>80%	--	100	84.67	PASS

Further analysis is provided as follows:

**Table 3: FHR Results with 2.5% Type 1 error with a two-sided interval**

Subject	Novii SR	Doppler SR	FHR PA	FHR RMSE	FHR MAE
Average	88.81	88.24	88.08	5.7949	3.0346
SD	10.48	9.76	12.42	3.5692	2.0951
Lower CI two-sided 95%	84.90	84.60	83.45	4.4642	2.2535

Upper CI two-sided 95%	92.72	91.87	92.71	7.1256	3.8157
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**Table 4: MHR Results with 2.5% Type 1 error with a two-sided interval**

Statistical Parameters	SPO2 SR	MHR SR	MHR (PA)	MHR RMSE	MHR MAE
Average	95.96	99.96	98.15	2.6762	1.6695
std	10.17	0.12	2.01	1.1496	0.6401
Lower CI two-sided 95%	91.47	99.90	97.26	2.1679	1.3864
Upper CI two-sided 95%	100.46	100.01	99.04	3.1845	1.9525

This study demonstrates that the data collected from Novii+ Pod is as accurate and as reliable as the data collected by Doppler ultrasound, TOCO transducer, and pulse oximetry (SpO2) devices for monitoring MHR, FHR and UA. The results of the clinical study demonstrate that the performance of Novii+ Wireless Patch System is equivalent to that of the Doppler/TOCO/ SpO2 devices for pre-term subjects ( $\geq 34$  weeks + 0/7 days through 36 weeks + 6/7 days gestation) in terms of accuracy and reliability.

Additionally, the following clinical data was gathered in support of the Novii+ Wireless Patch system:

1. To support patients of different skin pigmentations, data was collected to demonstrate that there is no specific trend observed, indicating that the heart rate measurement from pulse oximetry sensors from the Corometrics device and Novii+ does not result in higher errors when used on subjects with darker skin pigmentation.

	Skin Pigmentation level					
	Light		Medium		Dark	
Fitzpatrick scoring level	I	II	III	IV	V	VI
Number of subjects	4	9	3	1	3	0
Percentage	18.1	40.9	13.6	4.5	13.6	0
Predicted values based on trend	-	-	-	-	-	2.573
Mean RMSE	2.05	2.58	1.68	2.29	2.99	2.573

2. To support the equivalence of the clinical performance of the Novii+ Wireless Patch System on patients with non-cephalic fetal presentations, additional bench testing data was provided. The results show that the polarity of the QRS complex does not impact the FHR output of the Novii+ algorithm.
3. To support the equivalence of the clinical performance of the MHR output of the Novii+ Wireless Patch System while using MCG Gold Standard (GS) (12-lead ECG data) as the comparator instead of a SpO2 device, additional bench testing data was provided to compare the mean Root

Mean Square Error (RMSE) and Mean Absolute Error (MAE) results from the clinical study to that of the mean RMSE & MAE results from a standard ECG database of adult heart rates:

Mean RMSE value is less than 2BPM and mean RMSE% value is less than 3.2BPM for both Novii and Novii+ devices. Also, the ratio between two RMSEs are less than 1.25, which is a passing criterion for accepting the comparison between Novii and Novii+ MHR values. The MAE and MAE% values between Novii+ and GS and Novii and GS. MAE and MAE% values are less than 1.6BPM for both Novii and Novii+.

The results provided above demonstrate the equivalence of the Novii+ new algorithm to the predicate Novii algorithm-derived MHR in terms of accuracy and reliability as compared to a Gold Standard (12-lead ECG data).

**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.