DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 27, 2014

Monica Healthcare
Carl Barratt
CEO
BioCity, Pennyfoot Street
Nottingham, NG1, 1GF, UK

Re: K140862
Trade/Device Name: Monica 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 25, 2014
Received: July 28, 2014

Dear Carl Barratt,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known):

Device Name: Monica Novii Wireless Patch System

Indications For Use:

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 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 >36 completed weeks, in labor, 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 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.

The Novii Pod maternal-fetal monitor and its accessories are intended for use by healthcare professionals in a clinical setting

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

Monica Novii Wireless Patch System

Submitters Name:

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Email: carl.barratt@monicahealthcare.com

Name of Device: Monica Novii Wireless Patch System

Manufactured by:

Monica Healthcare Ltd
Biocity
Pennyfoot Street
Nottingham NG1 1GF
UK

Date of Summary: 25th July 2014

Classification Name: 21 CFR 884.270 System Monitoring Perinatal

Predicate Device:

Monica AN24 (K101801, K112390)
Monica IF24 (K112163)
Ambu Electrodes (K041026)

Device Description:

The Monica Novii Pod Fetal-Maternal Monitor 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 Monica 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 the Bluetooth connection to the Monica Novii CTG Interface device that is a Monica Approved accessory to the Monica Novii Pod.

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Intended Use:

The Monica Novii Pod is an intrapartum maternal-fetal monitor that non-invasively measures and displays fetalheart 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 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 >36 completed weeks, in labor, 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 NoviiPod 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.

The Novii Pod maternal-fetal monitor and its accessories are intended for use by healthcare professionals in a clinical setting

Technology Characteristics:

The Monica Novii Pod is a small battery powered electrophysiological monitor for the measurement of Maternal heart rate (MHR), Fetal heart rate (FHR) & Uterine activity (UA).

The electrical signals are passively monitored using five electrodes placed on the pregnant abdomen in a fixed array. From these electrical signals the Fetal Heart Rate (FHR), Maternal Heart Rate (MHR) and Uterine Activity (UA) are continuously extracted and displayed in the same standard format as the predicate device.

The detection technology of the Monica Novii Pod is identical to the Monica AN24 predicate device in that it use the same electronic components, the same signal processing software and detects the electrical RR Intervals in the same way. Both devices produce the same output i.e. fetal heart rate (expressed as number of heart beats per minute), uterine activity and maternal heart rate.

For the actual detection of FHR, MHR and UA the Monica Novii Pod does not emit any energy into the patient, the same as the predicate device and hence the detection technology does not raise any new type of safety and effectiveness questions. In addition for FHR, MHR and uterine activity both the Monica Novii Pod and predicate device are external, skin contacting devices. The materials in contact with the patient are biocompatibility tested and comply with standards. To ensure clinical effectiveness the clinical performance data was collected as described in the “Clinical Study” section below. This study demonstrates that the Monica Novii Pod device is at least as accurate and reliable as the predicate device for monitoring FHR, MHR and UA.

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Clinical Testing

The Monica Novii Patch was tested in a clinical environment in direct comparison to the AN24 predicate devices using individually placed Ambu electrodes used in accordance with the indications for use and Monica's AN24 user manual.

The clinical study monitored the clinical performance of the Monica Novii Patch and the predicate device for equivalence in 31 patients using a 60 minute recording for each participant, consisting of 30 minutes of data in stage 1 labor and 30 minutes of data in stage 2 labor (or late stage 1/stage 2 when stage 2 was shorter than 30minutes). The 30minutes segments were chosen without bias to the Novii Patch or AN24 performance. The clinical study was in two stages, 24 subjects recruited into three BMI groups and 7 subjects where the Novii Patch was deliberately misplaced.

The results demonstrated that the Monica Novii Patch is substantially equivalent to the Ambu electrodes attached to the Monica AN24 predicate device.

Non-Clinical Test Summary

Extensive bench testing of the Novii Pod, Interface and Patch was undertaken to establish their equivalence to the predicate devices and detailed reports are included in Appendix F. An overview covering the key elements of the bench testing is outlined below:

- **Data Transfer Validation (Plan 107-TP-007 & Report 107-TP-007_01)**

  These tests confirm data transfer reliability and accuracy under normal conditions and for wireless coexistence using the following process, see Figure 1

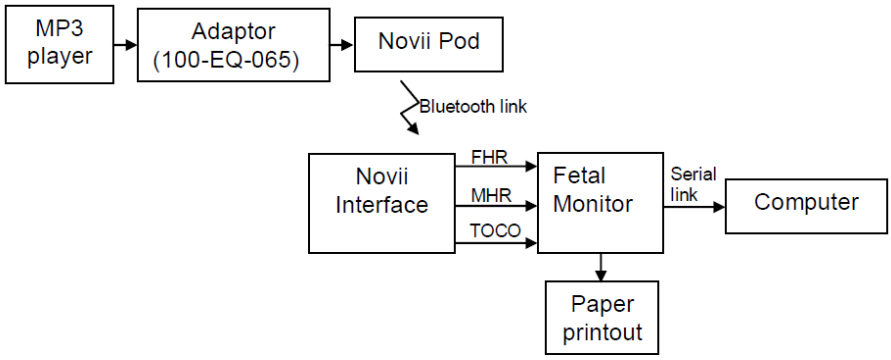

Figure 1: Data Transfer Validation

An MP3 player is used to simulate abdominal electrophysiological data on labouring patients. The simulated data is based upon data collected in a trial of the predicate Monica AN24 device (K101801). The audio MP3 output is fed into an adaptor (resistor network) to downsize the signals to microvolt levels in line with typical signal amplitudes recorded on the maternal abdomen. The Novii Pod detects the electrophysiological abdominal data and extracts FHR, MHR and Uterine Activity before transmitting it via Bluetooth to the Novii Interface. A Micro-SD card is fitted to the Novii Pod printed circuit board so that the Pod

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can store the extracted data locally for later comparison with the transmitted signal. The transmitted Bluetooth data is converted back to analogue signals upon collection by the Novii Interface and fed into a fetal monitor through its standard DECG, MECG and TOCO inputs. The fetal monitor sends the data to its serial interface in the normal way, where it is collected in real time by a computer. At the end of the test the data stored on the micro-SD memory card is downloaded to the computer and compared to the transmitted data collected in real time from the serial COM port of the fetal monitor. Reliability and accuracy of the data transfer is confirmed in this way by demonstrating it meets pre-set thresholds i.e. a bias difference less of than 1 BPM for fetal heart rate and a maximum loss of transmitted to recorded data of 2%

- **Data Extraction Validation (Plan 107-TP-004, Report 107-TR-001 and App A 107-TR-001)**

  The real time patient data extraction is verified by comparing the output of the predicate Monica AN24 device to the output of the Novii Pod in respect of FHR, MHR and UA data using simulated electrophysiological data.

  In the test, both devices are connected to the sound card of a computer using a resistor Bridge to reduce the voltage of the audio output of the PC soundcard down to the same level of amplitude recorded on the maternal abdomen. The data played through the PC sound card is simulated data based on data collected from the maternal abdomen in previous fetal ECG trials.

  Ten (10) data files are then played into the inputs of both devices simultaneously and the results of the extracted data is then compared to demonstrate equivalence by statistical analysis including; Positive Percent Agreement (PPA), Percentage Equivalence and Sensitivity

- **Other Bench Validation**

  In addition, testing was also undertaken to validate;

  - Interface software functionality, including pairing with and charging the Novii pods
  - Hardware for both the Pod & Interface to demonstrate size, weight, connection, IP rating and other aspects of the physical design.
  - Patch Validation Testing was carried out in accordance with the ANSI/ AAMI EC12 standard for disposable electrodes, covering; Peel & Tact, patch aging & storage, transportation and electrical performance such as internal noise

- **3rd Party Testing**

  In addition, the full Monica Novii Wireless Patch system was demonstrated to comply with voluntary standards at accredited independent test facilities in the following areas:

  - Electrical Safety (IEC60601-1)
  - EMC (IEC60601-1-2 & FCC CFR 47)

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- IP (BSEN 60529)
- Cleaning (Testing procedure is based on Ph Eur 2.6.13 / USP<61>)
- Biocompatibility (ISO10993)

Conclusion

The conclusions drawn from the non-clinical tests and clinical study demonstrate that the Monica Novii Wireless Patch System is as safe, as effective and performs as safely and effectively as the legally marketed predicate device.