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K101801 510(K) Summary

Monica AN24

Submitters Name:

Ian How
Monica Healthcare Ltd
Biocity
Pennyfoot Street
Nottingham NG1 1GF
UK

Tel: +44 (0)115 912 4541
Email: ianhow@monicahealthcare.com

Name of Device: Monica AN24

Manufactured by:

Monica Healthcare Ltd
Biocity
Pennyfoot Street
Nottingham NG1 1GF
UK

Date of Summary: 4th January 2011

Classification Name: 21 CFR 884.270 System Monitoring Perinatal

Predicate Device: Philips 50XM (K954351)

Device Description:
The Monica AN24™ is a small, battery-powered device for L&D surveillance of fetal well-being. The AN24™ is designed to passively monitor Fetal Heart Rate (FHR) from the fetal electrocardiogram (fECG) and Uterine Activity (UA) from the Electrohysterogram (EHG) during pregnancy and can be used at any time from > 36 completed weeks gestation in laboring patients. The AN24™ is suitable for singleton pregnancies only.

Intended Use:

The Monica AN24 is an intrapartum maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR) and uterine activity (UA). The AN24 acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the AN24 also acquires and displays the UA tracing from the uterine electromyography (EMG) signal. The AN24 is indicated for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.

The AN24 maternal-fetal monitor is intended for use by healthcare professionals in a clinical setting.

Technology Characteristics:
The Monica AN24 is a small, battery powered electrophysiological monitor (specifically fetal ECG and uterine EMG). The electrical signals are passively monitored on three channels using five electrodes placed on the pregnant abdomen in specific locations. From these electrical signals the Fetal Heart Rate (FHR) and

Uterine Activity (UA) are continuously extracted and displayed in **the same standard format** as the predicate device.

The detection technology of the Monica AN24 differs from the predicate device which uses Doppler ultrasound to measure Fetal Heart Rate (FHR) and a tocodynamometer (TOCO) to measure Uterine Activity (UA). The predicate device detects the mechanical RR interval of the fetal heart whilst the Monica AN24 detects the electrical RR interval. However, from this data both instruments produce the same output i.e. fetal heart rate (expressed as number of heart beats per minute).

Uterine activity in the Monica AN24 is derived from the electrohysterogram which is the electric signal of the contracting/moving uterine muscle. The uterine activity in the TOCO predicate is derived from an external strain gauge to measure the abdominal pressure of the contracting/moving uterine muscle. However from this data both instruments produce the same uterine activity output trace.

For the actual detection of both FHR and UA the Monica AN24 does not emit any energy into the patient and hence the above differences in detection technology do not raise any new type of safety and effectiveness questions. In addition for FHR and uterine activity both the AN24 and predicate device are external, skin contacting devices. Differences in materials in contact with the patient are resolved with biocompatibility testing and compliance 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 AN24 device is at least as accurate and reliable as the predicate device for monitoring both FHR and UA.

In summary, the differences in technology between the AN24 and the predicate device do not affect safety or effectiveness.

Clinical Study

1. Introduction

This section summarizes the six-way clinical equivalence trial and subsequent Multi-Reader-Multi-Case (MRMC) study1 supporting the effectiveness of the Monica AN24. The study enrolled 60 women at term, in labor, at two clinical sites, of which 33 women contributed to the Fetal Heart rate (FHR) study and 30 to the Uterine activity (UA) study. Each study subject was instrumented with three technologies for measuring fetal heart rate (FHR) and with three technologies for measuring uterine activity (UA). These are:

Fetal Heart Rate (FHR):

1) Doppler ultrasound cardiotocograph (Philips Series 50XM) – predicate device
2) Monica AN24 abdominal fetal ECG – test device
3) Direct fetal Scalp ECG (second Phillips Series 50XM device) – gold standard (GS)

Uterine Activity (UA):

1) Tocodynamometry (Philips Series 50XM) – predicate device
2) Monica AN24 Electrohysterogram (EHG) - test device
3) Intrauterine Pressure Catheter (IUPC), Philips Series 50XM – gold standard (GS)

Using fetal scalp electrode and IUPC as the "gold standards", this study methodology allowed a six-way comparison for evaluating how well the Monica AN24 performed vs. Doppler for FHR measurement and Monica AN24 versus tocodynamometry for uterine activity.

2. Study Design

2.1 Study Objective

The primary objective was to demonstrate that during the intrapartum period the Monica AN24 is equivalent to the Doppler FHR and tocodynamometer-derived uterine activity when both are compared simultaneously to direct scalp FHR and IUPC uterine activity, respectively.

Inclusion Criteria:

- Pregnant, age 15-40
- Term gestation (>36 completed weeks)
- Singleton fetus
- Active labor
- Vertex presentation
- Requiring internal monitoring

Exclusion Criteria:

- Clinical contraindication for IUPC
- Major fetal malformation

2.2 Study Methodology

Each study subject agreed to be simultaneously instrumented with three different technologies for measuring FHR and with three different technologies for measuring uterine activity (UA). Sensors and/or catheters were applied and removed as clinically indicated. For the UA comparison, three 30-minute segments of data were randomly selected from the entire monitored period for each subject, two 30-minute tracings from Stage 1 and one 30-minute trace from Stage 2 of labor. Therefore, 90 minutes of recording was analyzed for each subject for UA. For the FHR comparison, all the FHR data was analyzed for the entire monitoring period when the direct scalp FHR data was present.

2.3 Outcome Measures

Both the Monica AN24 (FHR and EHG) and the predicate devices (Doppler or TOCO) were compared with the gold standard (GS) device (i.e. direct scalp fetal ECG or IUPC). Monica AN24 was tested against the predicates using null hypotheses of inferiority and alternative hypotheses of non-inferiority, for the measurement of FHR and UA in terms of: Interpretability and *Accuracy* - resulting in four separate endpoints as follows:

Fetal Heart Rate

The data from all 3 FHR instruments was processed into synchronized 0.25 second epochs. The following primary end points were calculated for FHR:

End Point 1: For *FHR* interpretability the Monica FHR (or the Doppler FHR) versus the GS was organized into a 2x2 table of interpretable and uninterpretable data, i.e., where uninterpretable data are defined as those where the device in question does not report a valid FHR reading. A positive percent agreement (PPA) with GS was generated for each patient giving two values per patient – one for Monica AN24 vs GS and one for Doppler vs GS. PPA is defined as the percent of epochs with valid GS figures that are interpretable by the device in question

End Point 2: For FHR *accuracy*, a single Bland Altman (BA) difference plot was generated for Monica FHR (or Doppler FHR) vs the GS for each patient and a root mean square (RMS) error was determined for each device comparison. A BA difference plot is a scatter plot of the difference between the device and GS measurements vs. the GS measurement. RMS error is the square root of the mean of the squared differences.

Uterine Activity

The uterine activity data were independently reviewed in a Multi-Reader Study by four Board Certified Obstetricians who independently indicated on randomized trace segments the following features: "*Interpretable or Un-interpretable*" data, and "*Individual Contractions*", with each individual contraction marked as "*Good Quality*" or "*Bad Quality*". The marking was blind with respect to the device that produced the tracing. The four sets of data were again processed in terms of interpretability and accuracy. The following primary end points were calculated for UA:

End Point 3: For *UA interpretability*, a 2x2 Table of interpretable/uninterpretable data of Monica EHG (or TOCO) vs GS (IUPC) was constructed and the PPA was determined in the same manner as for FHR.

End Point 4a: For UA sensitivity accuracy, a Table of individual contractions identified by both Monica AN24 (or TOCO) and GS (IUPC) and those detected only by GS (IUPC) was constructed. To determine sensitivity, the proportion of contractions as determined by GS that were detected within ± 30 seconds by the device in question were calculated

End Point 4b: A second UA accuracy parameter (UA timing accuracy) was calculated as the difference in timing of corresponding contractions between Monica AN24 (or TOCO) and the GS (IUPC).

3. Description of Study Population

Thirty-four of 60 subjects enrolled provided evaluable data. Mean gestational age was 39 weeks 3 days (37 w 2d to 42 w 0d). Mean age was 26 years (18 to 38). Mean body mass index (BMI) was 32 (19 to 54). Thirty-one subjects were successfully instrumented with all six technologies, two subjects were successfully instrumented with three FHR technologies and one subject was successfully instrumented with three uterine activity technologies.

4. Results

The following key statistical outcomes, all validated with 95% confidence limits, were:

FHR compared to fetal scalp ECG

1. FHR Interpretability: The mean positive percent agreement (PPA) for interpretable data for Monica was 85% compared with 72% for Doppler
2. FHR Accuracy: The mean RMS error from Bland Altman was 5 bpm for Monica compared with 12 bpm for Doppler, indicating that the Monica AN24 FHR output is more similar to the gold standard fetal scalp electrode measurement compared to Doppler.

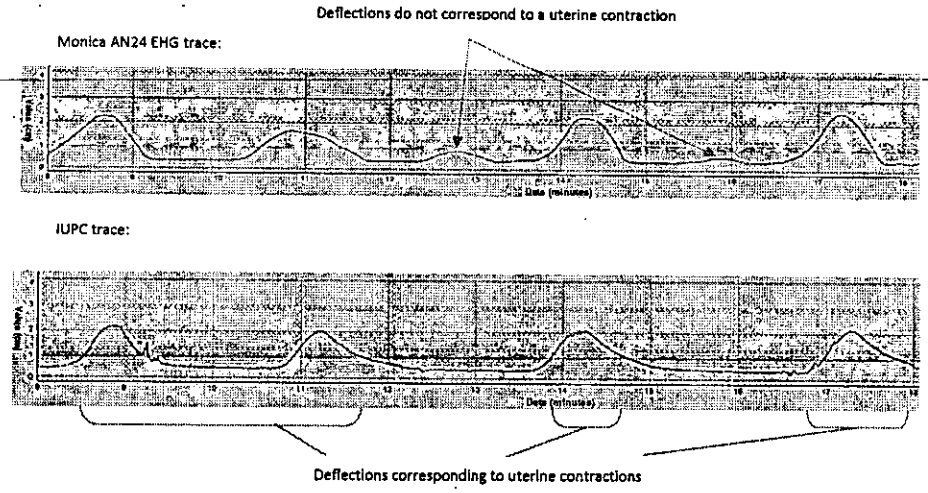
Uterine Activity compared to IUPC (average of 4 board certified obstetricians):

1. UA Interpretability: The mean PPA for UA trace interpretability of Monica was 97% compared with 67% for TOCO
2. UA Sensitivity Accuracy: The mean sensitivity for detecting individual contractions observed on IUPC, within ± 30 seconds, was 89% (84% to 91%) for Monica compared with 55% (48% to 62%) for TOCO.
3. UA Timing Accuracy: The mean timing difference of corresponding contractions was 2.5 seconds lag (2.06 to 2.94 seconds lag) when comparing Monica AN24 with IUPC and 3.3 seconds lag (2.92 to 3.69 seconds lag) when comparing TOCO with IUPC.

5. False Positives

When Monica AN24 or tocodynamometry tracings exhibit a deflection above baseline that does not have a corresponding deflection on the gold standard IUPC, that deflection may be considered a "False Positive" (FP). The Monica "Multi-Reader Study" evaluated the relative FP rate for Monica AN24 and tocodynamometry. The results of this analysis demonstrated that clinician judgement on individual deflections varied widely among the four clinical reviewers. Therefore, it is unclear whether comparison of the FP rate for Monica AN24 vs. tocodynamometry in the Multi-Reader Study is generalizable.

To illustrate how individual clinical judgment may vary, the following example displays a Monica AN24 tracing with two discernable deflections above baseline that do not correspond to deflections on the IUPC tracing:



If most or all of the types of Monica AN24 deflections above are counted as contractions, then the Monica AN24 may display more FP contractions compared to

tocodynamometry. This difference, however, is unlikely to have an adverse impact on clinical outcomes in full term laboring patients.

5. Acknowledgements

Monica Healthcare Ltd, UK, would like to thank: the clinical teams at QHC, New York and Temple University, Philadelphia for undertaking this study and the USA mothers who kindly agreed to take part in the study.

Non Clinical Test Summary

The Monica AN24 and Accessories comply with voluntary standards. The standards were employed in the following areas:

- Electrical Safety
- EMC
- Material Safety
- Software Validation

Conclusion

The non clinical tests used voluntary standards employed at accredited independent test facilities to demonstrate that the Monica AN24 is as safe and effective in performance to the predicate device, the main standards employed were

- IEC60601-1 electrical safety
- IEC60601-1-2 EMC
- IEC 60601-1-2-47 Performance standard for electrocardiographs
- IEC60601-1-4 Software
- ISO10993 Biocompatibility
- ISO14385 QMS

To demonstrate that the Monica AN24 is as clinically safe and effective as the predicate device, the clinical study described above measured the clinical performance of the Monica AN24 and the predicate device against the gold standards fetal scalp ECG and IUPC. The outcomes showed that in a clinical setting the Monica AN24 achieved for FHR: a positive percent agreement (PPA) for interpretability of 85% compared to 72% for the predicate; whilst for accuracy a mean RMS error from Bland Altman of 5 bpm for Monica AN24 when compared with 12 bpm for the predicate. For Uterine Activity the Monica AN24 achieved: a mean PPA for interpretability of 97% compared with 67% for predicate (TOCO); whilst for accuracy the mean sensitivity for detecting individual contractions was 89% for Monica AN24 compared with 55% for the predicate (TOCO); further the mean timing difference of corresponding contractions was 2.5 seconds (lag) when comparing Monica AN24 with IUPC and 3.3 seconds (lag) when comparing TOCO with IUPC. The Monica AN24 had an increased false positive contraction count compared to the predicate however, this was not clinically significant.

The conclusions drawn from the nonclinical tests and clinical study demonstrate that the Monica AN24 is as safe, as effective and performs as safely and effectively as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. Ian How
Regulatory Affairs Manager
Monica Healthcare
Biocity
Pennyfoot Street
Nottingham
United Kingdom NG1 1GF

FEB - 3 2011

Re: K101801
Trade Name: Monica AN24
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM, OSP
Dated: December 1, 2010
Received: December 3, 2010

Dear Mr. How:

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, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K101801

Device Name: AN24

Indications For Use:

The Monica AN24 is an intrapartum maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR) and uterine activity (UA). The AN24 acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the AN24 also acquires and displays the UA tracing from the uterine electromyography (EMG) signal. The AN24 is indicated for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.

The AN24 maternal-fetal monitor is 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101801