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K112390 510(K) Summary

Monica AN24

JUL 13 2012

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: 21st May 2012

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)), maternal heart rate (MHR) and Uterine Activity (UA) 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), maternal heart rate (MHR) and uterine activity (UA). The AN24 acquires and displays the FHR & MHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) and maternal ECG (mECG) 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, maternal 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), 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 AN24 differs from the predicate device which uses Doppler ultrasound to measure Fetal Heart Rate (FHR) and maternal heart rate (MHR), and a tocodynamometer (TOCO) to measure Uterine Activity

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(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 and maternal 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 FHR, MHR 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, MHR 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

Introduction

This section summarizes the clinical equivalence trial 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 Matrenal Heart Rate (MHR), the key statistics are :

Study Design

Study Objective

The study was designed as a prospective, equivalence study (for FDA approval purposes) for determining the performance of a trans-abdominal fetal ECG/EHG monitor (Monica AN24) when compared with an external Doppler ultrasound/tocodynamometer CTG monitor (Philips 50XM) during the first and second stage of labour. No additional invasive monitoring was performed purely for this study. Additionally, the maternal heart rate was monitored by a pulse oximeter, and it is this data that is used here to demonstrate MHR equivalence.

Inclusion Criteria:

The inclusion criteria were: subjects with singleton, term (≥ 37 weeks) pregnancies, giving birth in the hospital, who were able to be simultaneously monitored with Monica AN24 (FHR + UA), Doppler U/S FHR, Scalp ECG FHR, Toco UA, and IUPC UA, and who required internal monitoring (ie scalp ECG and/or IUPC).

Exclusion Criteria:

Subjects were excluded if: any transducer could not be optimally placed; if the fetus had a confirmed major malformation or chromosomal abnormality; if the subject had been involved in another clinical trial during this pregnancy; or if in the investigators opinion the subject was in a bad condition or otherwise not capable of taking part.

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Study Methodology

The Monica AN24 has been demonstrated to be substantially equivalent to existing predicate devices for monitoring of FHR and UA during labor and delivery (FDA clearance under K101801). However, the AN24 can also produce an MHR trace, which can be clinically useful either for maternal monitoring, or to identify fetal heart rate confusion if it occurs. This study demonstrates the equivalence of the Monica AN24 to a predicate SPO2 pulse oximeter (Philips M1191A) which produces an MHR trace when connected to a series 50 fetal monitor.

The study demonstrates that the alternative monitoring technique (maternal ECG monitoring), as used by the Monica AN24, is equivalent to the predicate. This includes showing that the device itself is capable of making these recordings safely and effectively, that the electrode positioning used for fetal monitoring (ie abdominal electrodes) does not prevent detection of the maternal ECG, and that the presence of the fetal ECG in the signal does not prevent accurate detection of the MHR from the ECG signal.

Outcome Measures

Both the Monica AN24 (MHR) and the predicate devices (Sp02) were compared. Monica AN24 was tested against the predicates using null hypotheses of inferiority and alternative hypotheses of non-inferiority, for the measurement of MHR.

Results
This section summarizes the results that confirm equivalence between Monica AN24 and the existing predicate device.

Maternal Heart Rate Equivalence:

Labor and Delivery:

- Reliability: Success rate:
  - AN24 MHR Mean SR: 99.3%
  - SPO2 MHR Mean SR: 87.8%
  - SR Ratio (AN24/SPO2) Mean: 1.16, CI: 1.08 - 1.21
    - Lower limit of CI > 0.8, so **equivalence criterion met**

  (Note: log transform applied to calculate CI due to skew)

- Accuracy: RMS error
  - Combined RMS error between AN24 and SPO2 mean: 4.49 BPM, CI: 3.46 - 5.52 BPM
  - Correlation between AN24 and SPO2 MHR traces mean: 0.90, CI 0.87 - 0.93
  - The 95% limits of agreement are -11.47 bpm to +11.62 bpm. We estimate the maternal heart rate measured by the AN24 to be between 11.47 bpm less than the Sp02 and 11.62bpm greater.

Statement of Equivalence

The results shown in Section meet the accuracy and reliability criteria for substantial equivalence. This demonstrates that the Monica AN24 is substantially equivalent to an SPO2 pulse oximeter for monitoring maternal heart rate during labor and delivery.

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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 against the predicate device. The Monica AN24 showed that in a clinical setting

The mean AN24 reliability is 99.3% ($CI_{95\%}$ = 98.5%; 100%).

The mean SPO2 reliability is 87.8% ($CI_{95\%}$ = 83.2%; 92.5%).

Reliability is measured by the difference of the success rates of the AN24 MHR and SPO2 MHR for each patient.

The mean MHR RMS error is 4.489 BPM ($CI_{95\%}$ = 3.416 BPM; 5.562 BPM).

Note that this RMS error is comparable to values given by the manufacturers of SPO2 sensors for MHR accuracy in the presence of movement (GE/Masimo sensor, pulse rate error (±1 S.D.) of ±3 BPM with no motion, or ±5 BPM with motion [4]).

The mean Pearson correlation coefficient (secondary statistics) is 0.9 ($CI_{95\%}$ = 0.877; 0.924).

The higher limit of the 95% CI of the MHR RMS error is 5.381 BPM, lower than the 7BPM equivalence threshold and accuracy equivalence is demonstrated.

The 95% limits of agreement are -11.47 bpm to +11.62 bpm. We estimate the maternal heart rate measured by the AN24 to be between 11.47 bpm less than the Sp02 and 11.62bpm greater.

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

Public Health Service

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

Mr. Ian How
Regulatory Affairs Manager
Monica Healthcare Ltd.
Biocity, Pennyfoot Street
NOTTINGHAM NG1 1GF
UNITED KINGDOM

JUL 13 2012

Re: K112390
Trade/Device Name: AN24
Regulation Number: 21 CFR§ 884.2720
Regulation Name: External uterine contraction monitor and accessories
Regulatory Class: II
Product Code: OSP
Dated: July 3, 2012
Received: July 5, 2012

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,

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: AN24

Indications for Use

The Monica AN24 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 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 and the MHR tracing from the maternal ECG signal (mECG). 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.

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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 K112390