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 6, 2015

OB Tools, LTD
% Paul Dryden
Regulatory Consultant
ProMedic, Inc.
24301 Woodsage Drive
Bonita Springs, FL 34134

Re: K150398
Trade/Device Name: EUM 100Pro
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM; OSP
Dated: July 6, 2015
Received: July 7, 2015

Dear Paul Dryden,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150398

Device Name

EUM 100Pro

Indications for Use *(Describe)*

The EUM100Pro (Electro Uterine Monitor) is a transabdominal electromyography (EMG) monitor intended to non-invasively measure intrapartum uterine activity and fetal heart rate (FHR). The EUM100Pro acquires the signal from surface EMG electrodes placed on the patient abdomen.

The EUM100Pro is intended for use on women (>36 completed weeks of gestation) in labor, with singleton pregnancies.

The EUM100Pro is intended for use by healthcare professionals in a clinical setting.

Type of Use *(Select one or both, as applicable)*

[X] 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

Date Prepared: 4-Aug-15

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Official Contact: Dr. Gal Ben-David
CEO

Proprietary or Trade Name: EUM 100Pro (Electro Uterine Monitor)

Common/Usual Name: External uterine contraction monitor with Fetal Heart Rate

Classification Name: External uterine contraction monitor
OSP – 21CFR 884.2720
Class II
Perinatal monitoring system and accessories
HGM - 21 CFR 884.2740
Class II

Predicate Device: K101801 – Monica Healthcare – AN24
Reference Device: K131889 – OB Tools EUM 100Pro

Device Description:
The EUM100Pro (electro uterine monitor) System is designed to present and transmit via RS232 protocol the electrical activity of the uterus and fetal heart rate. The data is shown and displayed as graphs (uterine activity and FHR) and similar to the commonly use toco-dynamometer / Doppler monitors.

The EUM100Pro is built around an EN 60950 certified computer.

Indications for Use:
The EUM100Pro (Electro Uterine Monitor) is a transabdominal electromyography (EMG) monitor intended to non-invasively measure intrapartum uterine activity and fetal heart rate (FHR). The EUM100Pro acquires the signal from surface EMG electrodes placed on the patient abdomen.

The EUM100Pro is intended for use on women (>36 completed weeks of gestation) in labor, with singleton pregnancies.

The EUM100Pro is intended for use by healthcare professionals in a clinical setting.

Comparison to Predicates

Tables 1 and **2** lists the similarities and differences of the predicates and the proposed device.

Table 1 - Table of the Similarities and Differences of Predicates vs. Proposed Device

	Predicate **Monica AN24 – K101801**	**Proposed device** **EUM 100Pro**
Procode	HGM / OSP	HGM / OSP
Name	External uterine contraction monitor External Fetal Heart Rate monitor	External uterine contraction monitor External Fetal Heart Rate monitor
CFR	884.2740 / 884.2720	884.2740 / 884.2720
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 AN 24 also acquires and displays the UA tracing from the uterine electromyography (EMG) signal and the MHR tracing from the maternal ECG signal (mECG).	The EUM100Pro (Electro Uterine Monitor) is a transabdominal electromyography (EMG) monitor intended to non-invasively measure intrapartum uterine activity and fetal heart rate. The EUM100Pro acquires the signal from surface EMG electrodes placed on the patient abdomen.
Patient population	It is intended for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen	The EUM100Pro is intended for use on women (>36 completed weeks of gestation) in labor, with singleton pregnancies.
Prescriptive	Trained medical personnel	Trained medical personnel
Environments of use	Clinical settings	Clinical settings
Power source	Battery	Mains power with isolation transformer
Method of measuring FHR	External surface EMG electrodes	External surface EMG electrodes
Display of information	Graphical	Graphical
Patient interface	Surface electrodes	Surface electrodes
Single patient use, disposable	Yes	Yes
Contraindications and Warnings	None	Patient with implanted electronic devices Open wounds or irritated skin Allergies to silver
Safety Testing	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-2-47	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-40
Clinical Testing for Fetal Heart Rate	Comparison to Fetal scalp electrode (FSE)	Comparison to Corometric Model 171 (reference device K991905) Fetal scalp electrode (FSE)

Substantial Equivalence Discussion
The EUM 100Pro is viewed as substantially equivalent to the predicate devices because:

Indications –

- The EUM 100Pro is indicated for as a transabdominal electromyography (EMG) monitor intended to measure fetal heart rate and intrapartum uterine activity.
- **Discussion** – This is identical to the predicate - K101801 – Monica AN24.

Patient Population –

- It is intended for use on women who are (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen
- **Discussion** – The patient population is identical to the predicate - K101801 – Monica AN24.

Environment of Use –

- For use in clinical settings by trained medical personnel
- **Discussion** – The environments of use and personal are identical to the predicate - K101801 – Monica AN24.

Technology –

- The use of transabdominal electromyography (EMG) signals to sense fetal heart rate (FHR) and uterine activity via an array of surface electrodes placed on the maternal abdomen.
- **Discussion** – This technology is identical to the predicate - K101801 – Monica AN24

Non-clinical Testing Summary -

For the fetal heart rate (FHR) feature there is no bench testing, we performed comparative clinical testing vs. the predicates.

Biocompatibility of Materials –

- The materials in contact with the patient are the EMG electrodes which are off-the-shelf (K990356).
- **Discussion –** The EMG electrodes have been cleared for the intended use under K990356 and in the reference device – K131889 – OB Tools EUM 100Pro.

Electrical, EMC, EMI testing –

- The proposed change to add the FHR feature was software only and there was no change in the electrical design of the reference device EUM 100Pro (K131889).
- **Discussion –** The proposed device is identical to the reference device - K131189 OB Tools EUM 100Pro.

Clinical Testing Summary -

We performed a comparative clinical study that was to show non-inferiority of the EUM100Pro with Fetal Heart Rate (FHR) as compared to the GE Corometrics Series 170 (K991905) and a fetal scalp electrode.

A clinical study was completed in order to show the non-inferiority of the EUM100Pro in monitoring fetal heart rate compared to Doppler based Fetal Monitor.

Thirty three women at term, during active labor, were enrolled**;** each subject enrolled was instrumented with three technologies for measuring fetal heart rate (FHR) as follows:

- EUM100Pro - Test device
- Scalp electrode connected to Philips HP 50 XM - Gold standard
- GE/Corometrics 170 Doppler ultrasound cardiograph - reference device

This study methodology allows comparison of the performance of EUM100Pro vs. Doppler as compared to the Scalp electrode gold standard.

Summary of Results

- There are significant differences in the PPA; **t**he mean positive percent of agreement for EUM was 98.5% 95%CI [98.5%-99.6%] compared with 96% 95%CI [95%-98.2%] for Doppler, demonstrating non-inferior results of the EUM as compared to Doppler in terms of percent of interpretable FHR.

- The mean RMS error from Bland Altman was 1.47 for EUM compared with 4.42 bpm for Doppler indicating that EUM is more similar to gold standard fetal Scalp electrode measurement compared to Doppler.

- The mean delta from Scalp is 0.009 95%CI [0.007-0.015] for EUM compared with 0.232 95%CI [0.227-0.256] for Doppler indicating that EUM is more similar to gold standard fetal Scalp electrode measurement compared to Doppler.

Discussion of Differences

A review of the differences for the proposed EUM 100Pro with the FHR feature as compared to the predicates and reference devices shows that there are no differences in indications for use, patient population, environments of use, design, technology and performance that would raises any new safety or effectiveness concerns.

510(k) Summary

4-Aug-15

Table 2 – Comparison to OB Tools EUM 100Pro (K131889) and the Proposed device

	Reference device **OB Tools EUM 100Pro – K131889**	**Proposed device** **EUM 100Pro**
Procode	OSP	HGM / OSP
Name	External uterine contraction monitor	External uterine contraction monitor External Fetal Heart Rate monitor
CFR	884.2720	884.2740 / 884.2720
Indications for Use	The EUM100Pro (Electro Uterine Monitor) is a transabdominal electromyography (EMG) monitor intended to non-invasively measure intrapartum uterine activity. The EUM100Pro acquires the signal from surface EMG electrodes placed on the patient abdomen.	The EUM100Pro (Electro Uterine Monitor) is a transabdominal electromyography (EMG) monitor intended to non-invasively measure intrapartum uterine activity and fetal heart rate. The EUM100Pro acquires the signal from surface EMG electrodes placed on the patient abdomen.
Patient population	The EUM100Pro is intended for use on women (>36 completed weeks of gestation) in labor, with singleton pregnancies.	The EUM100Pro is intended for use on women (>36 completed weeks of gestation) in labor, with singleton pregnancies.
Prescriptive	Trained medical personnel	Trained medical personnel
Environments of use	Clinical settings	Clinical settings
Power source	Mains power with isolation transformer	Mains power with isolation transformer
Method of measuring FHR	External surface EMG electrodes	External surface EMG electrodes
Display of information	Graphical	Graphical
Patient interface	Surface electrodes	Surface electrodes
Single patient use, disposable	Yes	Yes
Contraindications and Warnings	Patient with implanted electronic devices Open wounds or irritated skin Allergies to silver	Patient with implanted electronic devices Open wounds or irritated skin Allergies to silver
Safety Testing	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-40	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-40
Clinical Testing for Fetal Heart Rate	N/A	Comparison to Corometrics Series 170 (reference device) Fetal scalp electrode (FSE)

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.