510(k) Summary
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Date Prepared: 21-Apr-14

APR 2 3 2014

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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

Classification Name: External uterine contraction monitor
OSP – CFR 884.2720
Class II

Predicate Devices: K090145 – RRT – SureCALL®
K112390 – Monica Healthcare – AN24

Device Description:
The EUM100Pro System is designed to present and record the electrical activity of the uterus. The activity is shown as graphs similar to the commonly use toco-dynamometer.

The EUM100Pro is built around an EN- 60950 certified computer. Analog signals are obtained from CE certified amplifier box from Delsys Inc., Boston, MA. Delsys also supply the input modules, power supply, electrodes and disposable stickers.

The system is comprised of a multi-channel surface electromyogram operative to sense electromyographic (EMG) activity, a three-dimensional position sensor and a personal computer providing data analysis, recording media and a graphical user interface.

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

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

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Comparison to Predicates

	Predicate RRT SureCALL®	Predicate Monica AN24	Proposed device EUM 100Pro
510(k) number	K090145	K112390	
Procode	OSP	OSP	OSP
Name	External uterine contraction monitor	External uterine contraction monitor External Fetal Heart Rate monitor	External uterine contraction monitor
CFR	884.2740	884.2720	884.2720
Indications for Use	SureCALL® EMG labor Monitor is a transabdominal electromyography (EMG) monitor intended to measure intrapartum uterine activity.	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. 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	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	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
Prescriptive	Trained medical personnel	Trained medical personnel	Trained medical personnel
Environments of use	Clinical settings	Clinical settings	Clinical settings
Power source	Mains power with laptop computer charger	Battery	Mains power with isolation transformer

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	Predicate RRT SureCALL®	Predicate Monica AN24	Proposed device EUM 100Pro
510(k) number	K090145	K112390	
Method of measuring contractions	External surface EMG electrodes	External surface EMG electrodes	External surface EMG electrodes
Display of information	Graphical	Graphical	Graphical
Patient interface	Surface electrodes	Surface electrodes	Surface electrodes
Single patient use, disposable	Yes	Yes	Yes
Contraindications and Warnings	None	None	Patient with implanted electronic devices Open wounds or irritated skin Allergies to silver
Safety Testing	Electrical safety	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	Comparison to Tocodynamometer IUPC	Comparison to Tocodynamometer IUPC	Comparison to Tocodynamometer IUPC

Substantial Equivalence Discussion

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

Indications –

- The EUM 100Pro is indicated as a transabdominal electromyography (EMG) monitor intended to non-invasively measure intrapartum uterine activity.

Discussion – This is identical to the predicates, except that the EUM 100Pro does not monitor additional features, i.e., FHR, MHR as does K112390 – Monica AN24, nor does it connect to other traditional sensors which can be displayed on its screen as does K090145 – RRT SureCALL® for HR, FHR, IUPC, or TOCO sensors.

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
  Discussion – The patient population is identical to the predicates - K112390 – Monica AN24 and K090145 – RRT SureCALL®

Environment of Use –

- For use in clinical settings by trained medical personnel
  Discussion – The environments of use and personal are identical to the predicates - K112390 – Monica AN24 and K090145 – RRT SureCALL®

Technology –

- The use of transabdominal electromyography (EMG) signals to sense uterine activity via an array of surface electrodes placed on the maternal abdomen.
  Discussion – This technology is identical to the predicates - K112390 – Monica AN24 and K090145 – RRT SureCALL®

Non-clinical Testing Summary -

We have performed a number of tests appropriate for the proposed device. These tests include:

Biocompatibility of Materials –

- The only 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.

Electrical, EMC, EMI testing –

- We have evaluated the proposed device per IEC 60601-1 and IEC 60601-2-40 and the device passed the requirements.
  Discussion – The proposed device met the requirements of the standards.

Clinical Testing Summary -

The sponsor conducted a clinical study enrolling 43 women at term gestation in active labor who agreed to simultaneous uterine activity monitoring with the EUM 100Pro, tocodynamometry (TOCO), and intrauterine pressure catheter (IUPC). For each study subject, two sets of tracings (one during the first stage and the other during the second stage of labor) consisting of EUM, TOCO, and IUPC were evaluated independently by three physicians who were masked to the technology used to acquire the tracings. Physicians were asked to annotate the tracings above

each deflection above baseline they considered to be a contraction. They were also asked to indicate the total number of uterine contractions on the tracing as well as to comment on the interpretability of the tracing. The study provided evidence that the EUM 100Pro performed substantially equivalently to the legally marketed predicate devices for detecting and displaying uterine activity in women at term gestation in active labor.

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.

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

April 23, 2014

OB Tools Ltd.
% Paul E. Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
Bonita Springs, FL 34134

Re: K131889
Trade/Device Name: EUM100Pro (Electro Uterine Monitor)
Regulation Number: 21 CFR§ 884.2720
Regulation Name: External uterine contraction monitor and accessories
Regulatory Class: II
Product Code: OSP
Dated: March 20, 2014
Received: March 27, 2014

Dear Paul E. 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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131889

Device Name
EUM100Pro (Electro Uterine Monitor)

Indications for Use *(Describe)*

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 is intended for use on women in term (>36 completed weeks of gestation) 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)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
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