REPRODUCTIVE RESEARCH TECHNOLOGIES, LP

JUN 2 8 2013

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the SureCALL® Labor Monitor®.

1. Company making the submission:

Name	Reproductive Research Technologies, LP
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2. Device Name

Trade/Proprietary Name:	SureCALL® Labor Monitor®
Common/Usual Name:	Transabdominal Uterine Electromyography Labor Monitor
Classification Name:	Monitor, Uterine Contraction
Regulation Number:	884.2720 and 884.2740
Product Code:	OSP

3. Predicate Device:

The SureCALL® Labor Monitor® is substantially equivalent to other Uterine Contraction Monitors in the market such as the SureCALL™ EMG Labor Monitor [K090145].

4. Intended Use Statement:

The SureCALL® Labor Monitor® is a transabdominal electromyography (EMG) monitor intended to measure uterine activity. It is intended for use on pregnant women who are at term (>36 completed weeks), with singleton pregnancies, using surface electrodes on the maternal abdomen. The device is intended for use by healthcare professionals in a clinical setting.

5. Description of Device:

The SureCALL® Labor Monitor® is a transabdominal electromyography monitor. The device consists of a Signal Conditioning Module specifically designed to collect, filter, and amplify the electromyographic (EMG) signal and a separate Control System to analyze, record, and display the EMG signal. In addition, the device has the option to record and display the input from standard FDA-cleared fetal heart rate sensor, intrauterine pressure catheter, and maternal heart rate sensor or tocodynamometers transducer device, alongside the EMG signal traces. The Signal Conditioning Module contains electronic components designed to receive a physiological signal from a set of Ag/AgCl surface electrodes placed on the subject's abdomen and amplify and filter the signal. The optional fetal heart rate, intrauterine pressure catheter, and maternal heart rate or tocodynamometer's signals originating and collected from FDA-cleared devices pass through the Signal Conditioning Module without modification. The Control System consists of an off-the-shelf laptop computer with a LabVIEW based program designed to collect, record and display electrical signals in a meaningful and easily quantifiable format.

6. Summary of the technological characteristics of the device compared to predicate device:

There is no change in device from the predicate SureCALL™ EMG Labor Monitor [K090145].

7. Testing:

Non clinical testing:

No new non-clinical testing was done since the SureCALL™ EMG Labor Monitor [K090145].

Clinical testing:

The new indications for use were substantiated by a comprehensive comparative clinical study and a follow-up multi-reader study with the SureCALL® Labor Monitor® and the tocodynamometer.

Results from the clinical comparative study show that:

1. With regard to uterine contraction detection, between-patient variance is 5.65 and within-patient variance is 72.89 with ICC of 0.96, suggesting that 96% of the variance is due to within-patient correlation and 4% variance is due to device to device variation.
2. The bootstrap agreement estimates for TOCO vs. SureCALL® RMS show that there was above 95% agreement between RMS and TOCO devices.
3. Overall mean peak difference between RMS and TOCO is 0.99 seconds (SE = 1.41), which is ***not*** significantly different from 0 at $\alpha = 0.05$ level (P = 0.4901)

Results from the multi-reader study show that:

1. The sensitivity ranged from 75.6% to 90.1% and the extra SureCALL® event rate ranged from 3.30 to 6.12 per hour among the readers in preterm patient.
2. The estimated individual agreement was 0.964 (>0.8) in preterm patients.

8. Rx or OTC

The SureCALL® Labor Monitor® is an Rx prescription device per 21 CFR Subpart D. The indication for use is for clinical settings only.

9. Conclusions:

Based on testing and comparison to the predicate devices, the SureCALL® Labor Monitor® has the same intended use, and is substantially equivalent to the predicate. The device performs as intended and does not raise any new safety or effectiveness issues.

Reproductive Research Technologies, LP

Jack N. McCrary
Managing Director

Date: June 27, 2013

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

June 28, 2013

Reproductive Research Technologies, LP
% Mr. J. Harvey Knauss
Delphi Consulting Group
1770 St. James Place, Suite 600
HOUSTON TX 77056

Re: K130002
Trade/Device Name: SureCALL® Labor Monitor®
Regulation Number: 21 CFR 884.2720
Regulation Name: External uterine contraction monitor and accessories
Regulatory Class: Class II
Product Code: OSP
Dated: May 20, 2013
Received: May 29, 2013

Dear Mr. Knauss:

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 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. 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

Indications for Use Statement

510(k) Number K130002

Device Name: SureCALL® Labor Monitor®

The SureCALL® Labor Monitor® is a transabdominal electromyography (EMG) monitor intended to measure uterine activity. It is intended for use on pregnant women who are at term (>36 completed weeks), with singleton pregnancies, using surface electrodes on the maternal abdomen. The device is intended for use by healthcare professionals in a clinical setting.

Prescription Use **YES** (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use NO (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

K130002