K090145
pg. 1 of 4

JAN 25 2011

REPRODUCTIVE RESEARCH TECHNOLOGIES, LP

1770 St James Place, Suite 600
Houston, Texas 77056-3433
(713) 680-0200 Telephone
(713) 680-0299 Fax
E-Mail: jmc@innovalp.com

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® EMG Labor Monitor®**.

1. Company making the submission:

Name	Reproductive Research Technologies, LP
Address	1770 St James Place, Suite 600 Houston TX 77056-3433
Telephone Fax	713-680-0200 713-680-0299
Contact E-mail	Jack N. McCrary jmc@innovalp.com

2. Device Name

Trade/Proprietary Name:	SureCALL® EMG Labor Monitor®
Common/Usual Name:	EMG Labor Monitor
Classification Name:	Uterine electromyographic monitor
Regulation Number:	884.2720
Product Code:	OSP

3. Predicate Devices:

Toco Lite Model TD-01 [K013477]
Fetalgard 3000 Fetal Monitor [K983395]

4. Indications for Use:

The SureCALL® EMG Labor Monitor® is a transabdominal electromyography (EMG) monitor intended to measure intrapartum uterine activity. 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 device is intended for use by healthcare professionals in a clinical setting.

5. Description of Device:

The SureCALL® EMG Labor Monitor® is a transabdominal electromyography monitor. The device consists of a Signal Conditioning Module specifically designed to collect, filter, and amplify the electromyographical (EMG) signal and a separate Control System to analyze, record, and display the EMG signal. In addition, the device records and displays the input from standard FDA-cleared maternal heart rate sensor, fetal heart rate sensor, intrauterine pressure catheter and tocodynamometer transducer devices, along side 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 heart rate, intrauterine pressure, and/or tocodynamometer 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 quantifiable format.

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

The difference from the predicate device is the type of input sensors. Predicate devices utilize strain gauges held in place with a belt. The SureCALL® EMG Labor Monitor® utilizes paste-on Ag/AgCl electrodes.

The SureCALL® EMG monitors contractions through the noninvasive detection of uterine myoelectric activity recorded from the abdominal surface, while the Tocodynamometer monitors contraction through the detection of pressure changes on the abdominal surface. Both of these physiological signals have the same origin event, i.e. electrical activity by the uterus; therefore either one can be measured to detect the presence of contractions.

7. Testing:

Testing of the SureCALL® EMG Labor Monitor® included functional performance, electrical safety, and clinical studies as outlined in FDA Guidance Documents, regulations, and by FDA reviewers. The SureCALL® EMG Labor Monitor® has successfully completed all required testing.

8. Clinical Studies

The primary study supporting the effectiveness of the SureCALL® monitor involved

20 women at term, in labor, at three clinical sites. Each study subject was instrumented with three technologies for measuring uterine activity:

(1) a tocodynamometer (toco) attached to the maternal abdomen
(2) a set of abdominal surface electrodes for uterine electromyography (SureCALL®), and
(3) an intrauterine pressure catheter (IUPC).

Using IUPC as the 'gold standard', this study methodology allowed a three-way comparison for evaluating how well the SureCALL® system performed vis-à-vis the toco technology.

After completion of this study, in a second study the three different monitor tracings were evaluated using multi-reader-multi-case (MRMC) methodology where each reader read all three tracings.

False Positives

When SureCALL® 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 MRMC Study evaluated the relative FP rate for SureCALL® and tocodynamometry. The results of this analysis demonstrated that clinician judgment on individual deflections varied so widely that it is unclear whether the comparison of the FP rate for SureCALL® versus toco in the MRMC Study is generalizable.

To illustrate how individual clinical judgment may vary, the following example displays a SureCALL® tracing with at least two discernable deflections above baseline which do not correspond to deflections on the IUPC tracing.

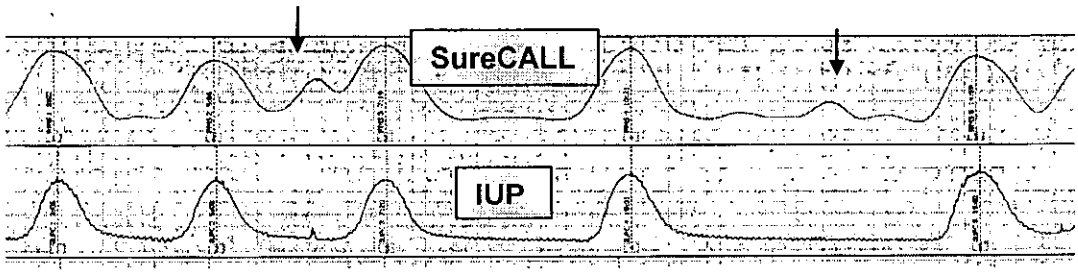

Figure 1: Aligned Tracings, SureCALL® and IUP

If most or all of the types of SureCALL® deflections in Figure 1 (above) are counted as contractions, then SureCALL® 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.

Summary

In summary, the three-way clinical study and the follow-up MRMC study demonstrate that the SureCALL® uterine EMG technology detects uterine contractions as well as conventional tocodynamometry. However, the technology infrequently presents low

amplitude deflections that may appear to be contractions but do not correspond to uterine contractions. These deflections may represent electrical activity in the myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract.

9. Rx or OTC

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

10. Conclusions:

Based on testing and comparison to the predicate devices, the SureCALL® EMG Labor Monitor® has the same intended use, and is substantially equivalent to the predicate devices. 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: January 10, 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Reproductive Research Technologies, LP
c/o Mr. J. Harvey Knauss
Consultant
Delphi Consulting Group
11874 South Evelyn Circle
HOUSTON TX 77071

JAN 25 2011

Re: K090145
Trade/Device Name: SureCALL EMG Labor Monitor
Regulation Number: 21 CFR §884.2720
Regulation Name: External uterine contraction monitor and accessories
Regulatory Class: II
Product Code: OSP
Dated: January 6, 2011
Received: January 7, 2011

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 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 K090145

Device Name: SureCALL® EMG Labor Monitor®

The SureCALL® EMG Labor Monitor® is a transabdominal electromyography (EMG) monitor intended to measure intrapartum uterine activity. 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 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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K090145