MAY 2 9 2014

510(K) SUMMARY FOR THE CLINICAL INNOVATIONS, LLC
Koala TOCO and Koala IUP/TOCO Reusable Cable

(per 21CFR 807.92 and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)

1. SUBMITTER/510(K) HOLDER

Clinical Innovations, LLC
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2. DEVICE NAME

Proprietary Name:	Koala TOCO and Koala IUP/TOCO Reusable Cable
Common/Usual Name:	Tocodynamometer and cable
Classification Name:	external uterine contraction monitor and accessories
Classification Panel:	Obstetrics/Gynecology
Device Class:	Class II
Classification Number:	21 CFR 884.2720
Product Code:	HFM, HFN

3. PREDICATE DEVICE

The following device is a legally marketed device to which equivalence is being claimed:

- FeatherLite™ Tocodynamometer (Ventrex, Inc., K013477)

4. DEVICE DESCRIPTION

The Koala TOCO is a single-use tocodynamometer that is a transducer pressure-sensing device that can detect the changes in a mother's abdomen as her uterus tightens during a contraction. The device detects how often contractions occur and the length of each.

The Koala TOCO device is a pneumatic tocodynamometer that comprises a guard-ring with a thin elastic membrane stretched across a shallow depression in the center

of the guard-ring. The elastic membrane traps a small volume of air in the depression. The air volume beneath the membrane of the Koala TOCO is connected via a low volume air channel to a pressure transducer in the Koala IUP/TOCO Reusable Cable. The operational response of the Koala TOCO is substantially equivalent to that of the standard guard-ring TOCO. This requires that the Koala TOCO have essentially the same physical shape, guard-ring area and pressure sensing area of the predicate devices. The pressure sensing area will present resistance to applied pressure. In other words, the displacement of air in the elastic membrane mimics the compression of the strain gauge of the guard-ring TOCO.

The Koala IUP/TOCO Reusable Cable can be used for intrauterine pressure monitoring with the Koala Intrauterine Pressure Catheter. The Koala TOCO and the Koala IUP/TOCO Reusable Cable are compatible with Philips and Corometrics monitors.

5. INDICATIONS FOR USE / INTENDED USE

The single-use disposable, non-sterile Koala TOCO is intended for use in conjunction with standard fetal monitors for the evaluation of relative external uterine activity during antepartum and intrapartum periods in a clinical setting.

The Koala IUP/TOCO Reusable Cable is also for use with the Koala Intrauterine Pressure Catheter for intrapartum, intrauterine pressure monitoring.

The Koala TOCO and Koala IUP/TOCO Reusable Cable are not intended for home monitoring of pre-term labor.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

A summary comparison of the technological characteristics, including design and materials, is provided in the table below:

Parameter	**Koala TOCO and Koala IUP/TOCO Reusable Cable (Clinical Innovations)**	**FeatherLite™ Tocodynamometer (Ventrex Inc.)**
510(k) Number	**K140163**	**K013477**
Indications for Use	For use in conjunction with standard fetal monitors for the evaluation of external uterine activity during antepartum and intrapartum periods in a clinical setting.	For use in conjunction with standard fetal monitors for the evaluation of external uterine activity during antepartum and intrapartum periods. It should only be used in a clinical setting.
Target Patient Population	Pregnant patients, especially during labor	Pregnant patients, especially during labor

Parameter	Koala TOCO and Koala IUP/TOCO Reusable Cable (Clinical Innovations)	FeatherLite™ Tocodynamometer (Ventrex Inc.)
Water environment use	No	No
Anatomical sites	Surface of abdomen over fundal area of the uterus	Surface of abdomen over fundal area of the uterus
Size	Body diameter: 7.0cm Body thickness: 0.8cm	Body diameter (sensing dome): 3.6cm Body thickness: .10cm Sensing dome thickness: .79cm
Weight (with cable)	0.35 lbs (159 g)	0.11 lbs (51g)
Material	Housing material: thermoplastic polyurethane Cable: Thermoplastic polyurethane	Housing material: thermoplastic Sensing nipple: flexible polymer Cable: vinyl clad
Technology	Sensing diaphragm connected to a pressure transducer centrally located in a circular (guard ring) body	Sensing nipple attached to a strain gauge
Sensor	Wheatstone resistive bridge sensor	Wheatstone resistive bridge sensor
Location of electronics	Housed in the reusable cable	Housed in the TOCO device
Serviceable	No	No
Patient attachment	Elastics belt included. Compatible with standard elastic belts.	Elastic belt included. Compatible with standard elastic belts.
Cable length	10 feet	8 feet
Single Use/Disposable	Yes	Yes
Biocompatible	Yes	Yes
Sterile	Non-sterile	Non-sterile

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Non-clinical testing performed to support the performance and safety claims for the Koala TOCO and the Koala IUP/TOCO Reusable Cable includes, but is not limited to, the following:

- Predicate comparison testing
- Simulated use testing
- Hardware testing
- Electrical performance testing
- Biocompatibility testing according to ISO 10993-1
- Intrauterine pressure catheter (IUPC) compatibility testing

The evidence resulting from the non-clinical testing supports the substantial equivalence of the proposed and predicate devices.

8. Summary of Clinical Testing as Basis for Substantial Equivalence

Not Applicable.

9. Summary of Other Information

This submission included proposed product labeling and packaging specifications.

10. Conclusions Drawn from Non-Clinical and Clinical Tests

The indications for use, principles of operation, and technological characteristics of the proposed Koala TOCO with the Koala IUP/TOCO Reusable Cable are substantially equivalent to the predicate device FeatherLite™ Tocodynamometer (subject of K013477). Differences between the proposed and predicate device are limited to minor differences in visual appearance, weight, sensing technology, and transducer location. These differences are minor and do not impact the safety and effectiveness of the device.

The safety, performance, and effectiveness of the Koala TOCO for its intended use are demonstrated by non-clinical testing. Based on the evidence provided, Clinical Innovations believes that the proposed Koala TOCO and Koala IUP/TOCO Reusable Cable are substantially equivalent to the predicate.

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

May 29, 2014

Clinical Innovations, LLC
% JoAnne L. Bronikowski
Consultant
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62 Forest Street, Suite 300
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Re: K140163
Trade/Device Name: Koala TOCO and Koala IUP/TOCO Reusable Cable
Regulation Number: 21 CFR§ 884.2720
Regulation Name: External uterine contraction monitor and accessories
Regulatory Class: II
Product Code: HFM, HFN
Dated: April 29, 2014
Received: April 30, 2014

Dear JoAnne L. Bronikowski,

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140163

Device Name
Koala TOCO and Koala IUP/TOCO Reusable Cable

Indications for Use *(Describe)*
The single-use disposable, non-sterile Koala TOCO is intended for use in conjunction with standard fetal monitors for the evaluation of relative external uterine activity during antepartum and intrapartum periods in a clinical setting.

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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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