May 22, 2025

Clinical Innovations LLC
Alex Garrett
Regulatory Affairs Specialist
747 W 4170 S
Murray, Utah 84047

Re: K250897
Trade/Device Name: Koala Intrauterine Pressure Catheter (IPC-5000E)
Regulation Number: 21 CFR 884.2700
Regulation Name: Intrauterine Pressure Monitor and accessories
Regulatory Class: III
Product Code: HFN
Dated: March 24, 2025
Received: March 25, 2025

Dear Alex Garrett:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250897

Device Name
Koala Intrauterine Pressure Catheter (IPC-5000E)

Indications for Use *(Describe)*
Koala Intrauterine Pressure Catheter is indicated for use on patients requiring intrapartum intrauterine pressure monitoring.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary – K250897
Koala Intrauterine Pressure Catheter

Applicant: Clinical Innovations, LLC
747 West 4170 South,
Murray, UT 84123, USA

Contact Person: Alex Garrett
Regulatory Affairs Specialist II
Phone: 1(800) 522-6743
Email: agarrett@laborie.com

Date Prepared: May 19, 2025

Device Information

Device Trade Name:	Koala Intrauterine Pressure Catheter (IPC-5000E)
Common Name:	Intrauterine Pressure Catheter
Regulation Name:	Intrauterine pressure monitor and accessories
Regulation Number:	21 CFR 884.2700
Product Code:	HFN (Transducer, Pressure, Intrauterine)
Regulatory Class:	Class II

Predicate Device Information

Device Name:	Koala Intrauterine Pressure Catheter
510(k) Number	K974389
Manufacturer:	Clinical Innovations LLC

The predicate device has not been subject to a design-related recall.

Device Description Summary

The Koala Intrauterine Pressure Catheter is a disposable, sterile, single patient use intrauterine pressure monitoring catheter, designed for measurement of intrauterine contraction pressures. The catheter is designed with a pressure-sensing membrane cavity at the tip (mounted externally), a port for amnioinfusion and amniotic fluid sampling, and an introducer which is removed after placement. The Koala Intrauterine Pressure Catheters utilizes a reusable cable with a reusable pressure transducer which is connected at the other end of the device.

The sensor, located on the tip of the catheter is a 360° sensor that registers pressure in all directions. The tip is made of soft, malleable urethane. There are no electronics in the catheter. Clinicians can disconnect the catheter while it is in the uterus and zero the monitor while the transducer is exposed to atmospheric pressure, providing a true zero reading.

The Koala Intrauterine Pressure Catheter has two different, clear lumens, one for the amnioinfusion, to confirm proper placement via amniotic fluid flashback, and another channel for sensor-charging. The amnioinfusion port has a hydrophobic and a tethered replacement cap.

Indications for Use

Koala Intrauterine Pressure Catheter is indicated for use on patients requiring intrapartum intrauterine pressure monitoring.

Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device.

Device & Predicate Device(s):	**Subject Device (K250897)** Koala Intrauterine Pressure Catheter (IPC 5000E)	**Predicate Device (K974389)** Koala Intrauterine Pressure Catheter	**Comparison**
Intended patient population	Patients requiring intrapartum, intrauterine pressure monitoring	Patients requiring intrapartum, intrauterine pressure monitoring	Same
Product Code	HFN	HFN	Same
Indication for Use	Koala Intrauterine Pressure Catheter is indicated for use on patients requiring intrapartum intrauterine pressure monitoring.	This catheter is for use on patients requiring intrapartum intrauterine pressure monitoring.	Similar
Prescription or OTC	Prescription	Prescription	Same
Principle of operation	Employs air coupling technology from a distally mounted flexible balloon in the uterus to an external, reusable transducer in the monitor cable and connector.	Employs air coupling technology from a distally mounted flexible balloon in the uterus to an external, reusable transducer in the monitor cable and connector.	Same
Air coupling channel	**Lumen with integrated element**	**Single lumen with microfilament inside attached at the ends of the tube.**	**Different**
Catheter Dimensions	Catheter Length: 30.5 Inches Catheter Outer Diameter: 0.136 Inches Catheter Inner Diameter: 0.103 Inches	Catheter Length: 30.5 Inches Catheter Outer Diameter: 0.136 Inches Catheter Inner Diameter: 0.103 Inches	Same
Use Condition provided	Sterile	Sterile	Same
Sterilization method	Gamma irradiation	Gamma irradiation	Same
Shelf-life	**6 months**	**2 Years**	**Different**
Use environment	Hospital or medical center	Hospital or medical center	Same
Storage conditions	**-25° C to +50° C**	**-25° C to +65° C**	**Different**

Performance specifications (with reusable cable)			
Transducer Type	Silicone Diaphragm	Silicone Diaphragm	Same
Operation Pressure Range	-50 to +150mmHg	-50 to +150mmHg	Same
Over-pressure Protection	-400 to +1200 mmHg	-400 to +1200 mmHg	Same
Operating Temperature	15º C to 40º C	15º C to 40º C	Same
Amnio Lumen flow	Min. 20 cc/min at a pressure of 65 mmHg	Min. 20 cc/min at a pressure of 65 mmHg	Same
Material composition			
Tubing (Bump tube)	**Polyurethane, Isothane 5065D**	**Polyurethane**	**Different**
Monofilament	**Removed (Polyurethane)**	**Nylon**	**Different**
Adhesive	Cyanoacrylate	Cyanoacrylate	Same
Adhesive (UV)	Polyurethane Oligomer	Polyurethane Oligomer	Same
Band (elastic)	C-flex	C-flex	Same
Membrane	Polyethylene/ethylene vinyl acetate (external)	Polyethylene/ethylene vinyl acetate (external)	Same
Catheter Body	**Polyurethane/Pebax, Isothane 5055D (as an alternative to Pellethane)**	**Polyurethane/Pebax (Polyamide based thermoplastic) co-extrusion. Pellethane 2363-55D.**	**Different**
Connector ('T' Barb)	Polycarbonate	Polycarbonate	Same
Ink, Black, Visprox	**Ink (added PrintSafe ink as an alternate material).**	**Ink**	**Different**
Introducer	**Ferro RxLOY polyolefin alloy, HIVAL 521054**	**Polyethylene**	**Different**
Cap	Polyvinyl Chloride	Polyvinyl Chloride	Same
Luer Cap (non- vented)	Polyethylene	Polyethylene	Same
Luer Cap (vented)	ABS	ABS	Same
Adhesive patch	Polyester	Polyester	Same

The indications for use of the subject and predicate devices are similar; therefore, they have the same intended use (i.e., for intrapartum measurement of intrauterine pressure).

The subject and predicate devices have similar technological features, including device design, operating principle, interface, device dimensions etc. However, as shown in the table above, the subject and predicate devices differ in terms of minor design changes, materials, storage temperature and shelf-life. These differences of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness.

Non-Clinical Performance Tests Summary and Conclusions

Biocompatibility testing

Biocompatibility testing of the final finished device was conducted in accordance with the 2024 FDA guidance "*Use of International standard ISO 10993-1, Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process*" fora surface devices contacting breached or

compromised surfaces for a limited time (<24 hours) with the following endpoints:

- Cytotoxicity per ISO 10993-5
- Sensitization per ISO 10993-10
- Irritation or intracutaneous reactivity per ISO 10993-23
- Acute systemic toxicity per ISO 10993-11
- Material mediated pyrogenicity per ISO 10993-11, USP<151>

The subject device was found to be non-cytotoxic, non-sensitizing, non-irritating, not systemically toxic, and non-pyrogenic (material mediated).

The following testing was conducted to support sterility and shelf-life of the subject device:

- Gamma radiation sterilization and validation testing per ISO 11737-1:2015, ISO 11737-2:2015, ANSI AAMI ST67:2019 and the 2024 FDA guidance "*Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile Guidance for Industry and Food and Drug Administration Staff*".
- Simulated transportation and associated package integrity testing in accordance with ASTM D4169-22 DC-13.
- Shelf-life testing (accelerated aging) per ASTM F1980:21, including package integrity testing (dye penetration test per ASTM F1929-15, seal strength testing per ASTM F88/F88M-21 and visual assessment per ASTM F1886/F1886M-16) and mechanical performance, as outlined in the functional testing below.

All device samples met their acceptance criteria, demonstrating the sterility and package integrity is maintained through the transportation and proposed shelf-life of the subject device.

Functional Testing

Following testing was conducted to assess the device performance after initial manufacturing (T=0) and following accelerated aging (T=six months):

- Simulated use (Ballon Pressure and Tip Pull-off force, with monofilament removal)
- Pressure accuracy
- Leak rate/ Membrane integrity
- T-connector bond strength
- Tip bond strength
- Catheter flexibility
- Introducer peel-force

All device samples met their acceptance criteria, demonstrating that when manufactured to specification, the device functions as intended throughout its specified shelf-life.

Conclusion

The performance testing described above demonstrate that the Koala Intrauterine Pressure Catheter (IPC 5000E) is as safe and effective as the predicate device and supports determination of substantial equivalence.