October 7, 2025

Clinical Innovations, LLC
Alexis Ross
Regulatory Affairs Specialist II
747 W 4170 S
Murray, Utah 84123

Re: K250298
Trade/Device Name: Kiwi® Complete Vacuum Delivery System, OmniCup® (VAC-DUAL M);
Kiwi® Complete Vacuum Delivery System, OmniCup® with Traction Force Indicator (VAC-DUAL MT);
Kiwi® Complete Vacuum Delivery System, OmniC Cup® for Cesarean Section (VAC-DUAL C);
Kiwi® Complete Vacuum Delivery System, ProCup® (VAC-DUAL S)
Regulation Number: 21 CFR 884.4340
Regulation Name: Fetal Vacuum Extractor
Regulatory Class: II
Product Code: HDB
Dated: January 31, 2025
Received: July 18, 2025

Dear Alexis Ross:

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: The Center for Devices and Readiological Health (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, The Food and Drug Administration (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,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250298

Device Name
Kiwi® Complete Vacuum Delivery System, OmniCup® (VAC-DUAL M); Kiwi® Complete Vacuum Delivery System, OmniCup® with Traction Force Indicator (VAC-DUAL MT); Kiwi® Complete Vacuum Delivery System, OmniC Cup® for Cesarean Section (VAC-DUAL C); Kiwi® Complete Vacuum Delivery System, ProCup® (VAC-DUAL S)

Indications for Use *(Describe)*

The Kiwi Complete Vacuum Delivery System (Kiwi® Complete Vacuum Delivery System, OmniCup® (VAC-DUAL M); Kiwi® Complete Vacuum Delivery System, OmniCup® with Traction Force Indicator (VAC-DUAL MT); Kiwi® Complete Vacuum Delivery System, OmniC Cup® for Cesarean Section (VAC-DUAL C); Kiwi® Complete Vacuum Delivery System, ProCup® (VAC-DUAL S)) is indicated for use in the following conditions:

- Prolonged second stage of labor (arrest of descent) where fetopelvic relationships are adequate
- Presumed fetal jeopardy that is not considered to be severe
- Elective shortening of the second stage for selected maternal or fetal conditions

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K250298

I. SUBMITTER

Applicant:	Clinical Innovations, LLC
Address:	747 West 4170 South, Murray, UT 84123, USA
Phone:	(360) 213-7652
Contact Person:	Alexis Ross, Regulatory Affairs Specialist II
Email:	aross@laborie.com

Date Prepared: October 3, 2025

II. DEVICE

Trade Name:	Kiwi® Complete Vacuum Delivery System, OmniCup® (VAC-DUAL M); Kiwi® Complete Vacuum Delivery System, OmniCup® with Traction Force Indicator (VAC-DUAL MT); Kiwi® Complete Vacuum Delivery System, OmniC Cup® for Cesarean Section (VAC-DUAL C); Kiwi® Complete Vacuum Delivery System, ProCup® (VAC-DUAL S)
Common Name:	Fetal vacuum extractor
Regulation Name:	Fetal vacuum extractor
Regulation Number:	884.4340
Product Code:	HDB (Extractor, Vacuum, Fetal)
Regulatory Class:	II

III. PREDICATE DEVICE

Kiwi Complete Vacuum Delivery System (K981260). The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The subject device is a fetal vacuum extractor (Kiwi® Complete Vacuum Delivery System) that includes four different models: OmniCup® (VAC-DUAL M); OmniCup® with Traction Force Indicator (VAC-DUAL MT); OmniC Cup® for Cesarean Section (VAC-DUAL C); ProCup® (VAC-DUAL S). All models use the same pump assembly, which allows the user to generate vacuum by squeezing the handle repeatedly. The pump/handle assembly includes a vacuum gauge that is color-coded to indicate safe operating pressures for the device. Models M and MT differ only in the inclusion of a traction force indicator (MT). Model C differs from models M/MT in the cup design, which has a lower profile cup with finger grooves to facilitate use in cesarean sections, as well as a baffle instead of an inner filter. The model S design is suggested for use in vaginal births and includes a combined tube and cup portion that is flexible and fits over the fetal head.

For vaginal delivery, the device is operated by inserting the cup into the vagina and placing the cup at the flexion point on the fetal skull. The Omni-C is designed specifically for the confined abdominal space of C-section deliveries. It is designed with a slimmer cup profile, finger grooves and baffle filter on the inside. For cesarean delivery, the cup is inserted into the incision over the flexion point.

V. INDICATIONS FOR USE

The Kiwi Complete Vacuum Delivery System (Kiwi® Complete Vacuum Delivery System, OmniCup® (VAC-DUAL M); Kiwi® Complete Vacuum Delivery System, OmniCup® with Traction Force Indicator (VAC-DUAL MT); Kiwi® Complete Vacuum Delivery System, OmniC Cup® for Cesarean Section (VAC-DUAL C); Kiwi® Complete Vacuum Delivery System, ProCup® (VAC-DUAL S)) is indicated for use in the following conditions:

- Prolonged second stage of labor (arrest of descent) where fetopelvic relationships are adequate
- Presumed fetal jeopardy that is not considered to be severe
- Elective shortening of the second stage for selected maternal or fetal conditions.

VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A comparison of the intended use and technological features of the subject and predicate device are described in the table below:

Comparison Item	K250298 Subject Device	K981260 Predicate Device	Comparison
Indications for Use	The Kiwi Complete Vacuum Delivery System (Kiwi® Complete Vacuum Delivery System, OmniCup® (VAC-DUAL M); Kiwi® Complete Vacuum Delivery System, OmniCup® with Traction Force Indicator (VAC-DUAL MT); Kiwi® Complete Vacuum Delivery System, OmniC Cup® for Cesarean Section (VAC-DUAL C); Kiwi® Complete Vacuum Delivery System, ProCup® (VAC-DUAL S)) is indicated for use in the following conditions: o Prolonged second stage of labor (arrest of descent) where fetopelvic relationships are adequate o Presumed fetal jeopardy that is not considered to be severe o Elective shortening of the second stage for selected maternal or fetal conditions.	Standard vacuum extraction use for fetal vacuum extraction in conditions of 1) prolonged second stage of labor (arrest of descent) where fetopelvic relationships are adequate, 2) presumed fetal jeopardy which is not considered to be severe, or 3) elective shortening of the second stage for selected maternal or fetal conditions. Trial of vacuum extraction vacuum delivery should be regarded as a "trial 1) if there is arrest of descent in the second stage and fetopelvic relationships are considered to be borderline, or 2) in a mid-pelvic extraction when position and station are known. Vacuum extraction should be abandoned, and birth completed by cesarean section 1) if no descent (progress) of the head occurs after 2 tractions, 2) if delivery is not achieved or imminent after 4	There are differences in the wording of the indications for use statements for the subject and predicate device; however overall, the indications for use statements for the predicate device are similar in intended use for fetal vacuum extraction.

Comparison Item	K250298 Subject Device	K981260 Predicate Device	Comparison
		tractions, or 3) if the vacuum cup detaches ("pops-off") twice.	
Conditions for Use	Prescription Use Only	Prescription Use Only	**Same**
Models	VAC-DUAL S, VAC-DUAL M, VAC-DUAL MT, VAC-DUAL C	Not available publicly	**Different:** The subject device and predicate devices have differences in models. These differences do not raise different questions of safety and effectiveness (S&E).
Overall Length	S 10.5” M 12.07” MT 13.87” C 12.24”	Not available publicly	**Different:** The differences in dimensional specifications do not raise different questions of S&E.
Handle width	4.20”	Not available publicly	**Different:** The differences in dimensional specifications do not raise different

Comparison Item	K250298 Subject Device	K981260 Predicate Device	Comparison
			questions of S&E.
Overall width	6.09”	Not available publicly	**Different:** The differences in dimensional specifications do not raise different questions of S&E.
Vacuum and traction generation	Palm pump with analog vacuum level indicator Traction force indicator (MT only)	Not available publicly	**Different:** The differences in performance specifications do not raise different questions of S&E.
Pull-off force	≥20 lbf at 450 mmHg	Not available publicly	**Different:** The differences in performance specifications do not raise different questions of S&E.
Recommended operational vacuum range	450-600 mmHg	Not available publicly	**Different:** The differences in performance specifications do not raise

Comparison Item	K250298 Subject Device	K981260 Predicate Device	Comparison
			different questions of S&E.
Sterilization	Gamma	Not available publicly	**Same**

As shown in the table above, there are differences in the indications for use statements and technological characteristics of the subject and predicate devices. However, as stated in the table, the differences in indications for use do not represent a new intended use and the differences in technological characteristics do not raise different questions of safety and effectiveness.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The following studies have been conducted in support of the substantial equivalence of the subject device to the predicate device:

- Radiation sterilization validation to demonstrate SAL of 10^{-6}, per ISO 11137-1:2006 (including: Amendment 1 (2013) and Amendment 2 (2018)) Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices and ISO 11137-2:2013 - Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose [Including Amendment 1 (2022)].
- Shelf-life testing was conducted to support a shelf-life of 12 months were met at time 0 and after accelerated aging per ASTM F1980:
  - Transportation testing per ASTM D4169-22 (DC 13) followed by packaging integrity evaluation for bubble leak and seal strength test.
  - Design verification performance testing including the following:
    - Grip dimensional testing
    - Cup/tubing dimensional testing
    - Vacuum Gauge accuracy
    - Full assembly leak test

- Bond strength (lbf)
- Pop-off force (lbf)
- Palm chamber actuation and retention (lbf)
- Traction gauge accuracy (MT only)
- Pressure generated by 3 pumps of handle (mmHg)
- Number of pumps to generate at least 450 mmHg
- Maximum vacuum pressure generated (mmHg)
- Leak rate (mmHg/min)
- Vacuum release time (s)

- Biocompatibility testing was conducted as the subject devices are surface devices in contact with a breached or compromised surface (contact duration <24h). Testing was conducted in accordance with the 2023 FDA guidance document Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process" and ISO 10993-1:2009 as follows:

  - Cytotoxicity (ISO 10993-5:2009/(R)2014)
  - Guinea Pig Maximization Sensitization Test (ISO 10993-10: 2021)
  - Intracutaneous Irritation (ISO 10993-23: 2021)
  - Acute systemic toxicity (ISO 10993-11:2017)
  - Material-mediated pyrogenicity (USP<151>)

  The results of the testing conducted support the biocompatibility of the patient contacting subject devices.

VIII. CONCLUSION

The results of the performance testing described above demonstrate that Kiwi® Complete Vacuum Delivery System is as safe and effective as the predicate device and supports a determination of substantial equivalence.